

**EPA Registration Number 9480-13**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

February 28, 2017

Melissa Louis-Juste  
Regulatory Affairs Associate  
Professional Disposables International, Inc. (PDI)  
100 Philips Parkway  
Montvale, NJ 07645

Subject: CSF Notification per PRN 98-10 – Minor modifications to Basic CSF  
Product Name: Backspin No-Rinse FCSS  
EPA Registration Number: 9480-13  
Application Date: January 27, 2017  
Decision Number: 525530

Dear Ms. Louis-Juste:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 01/20/2017

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, you may contact Joe Daniels at (703) 347-8669 or via email at [daniels.joseph@epa.gov](mailto:daniels.joseph@epa.gov).

Sincerely,

A handwritten signature in dark ink, appearing to read "E. Miederhoff".

Eric Miederhoff  
Product Manager 31  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs





United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address <b>Professional Disposables International, Inc. (PDI)</b> <b>100 Philips Parkway</b> <b>Montvale, NJ 07645</b>	EPA File Symbol/Registration Number <b>9480-13</b>
	Product Name <b>Backspin No-Rinse FCSS</b>
	Date of Confidential Statement of Formula (EPA Form 8570-4) <b>01/20/2017</b>

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

**n-Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride**  
**and**  
**Didecyl Dimethyl Ammonium Chloride**

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

- (3) Indicate by checking (A) or (B) below which paragraph applies:

- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
<b>n-Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride</b> <b>and</b> <b>Didecyl Dimethyl Ammonium Chloride</b>	<div style="background-color: black; width: 100px; height: 30px;"></div>	<div style="background-color: black; width: 100px; height: 30px;"></div>
Signature 	Name and Title <b>Melissa Louis-Juste</b>	Date <b>01/27/2017</b>

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
Copy 2 - Applicant copy

\*Product ingredient source information  
may be entitled to confidential

t t t\*



Two Nice-Pak Park  
Orangeburg, New York 10962  
pdihc.com

January 27, 2017

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
One Potomac Yard, 2777 S. Crystal Drive, Room S-4900  
Arlington, VA 22202

Attn: Eric Miederhoff, PM 31

**Re: Minor Formulation Amendment per PR Notice 98-10 to add alternate towelette and other minor changes to CSF. No PRIA Fee.**

**Product:** Backspin No-Rinse FCSS  
**EPA Reg. No:** 9480-13  
**Company:** Professional Disposables International, Inc.

Dear Mr. Miederhoff:

I am submitting this Minor Formulation Amendment per PR Notice 98-10 for Backspin No-Rinse FCSS CSF, EPA Reg. No. 9480-13 to make changes as follows:

Basic CSF:

- Changed Company's address
- Added EPA Reg.No.
- Added Alternate towelette
- Added EPA Producing Establishments

Enclosures

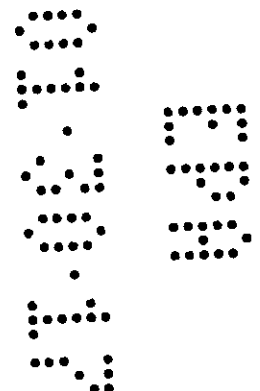
The following documents are enclosed in support of this application:

- EPA form 8570-1
- 2 copy of the Basic CSF; Copies are highlighted to show changes.
- Formulator's Exemption Statement
- 1 SDS

If you have any questions regarding this submission, please contact me at (201) 746-7958 or melissa.louisjuste@pdipdi.com.

Sincerely,

Melissa Louis-Juste  
REGULATORY AFFAIRS ASSOCIATE  
NICE-PAK PRODUCTS, INC  
PROFESSIONAL DISPOSABLES INTERNATIONAL (PDI) INC.  
100 PHILIPS PARKWAY, MONTVALE, NJ 07645  
P 201-746-8958  
Melissa.louisjuste@pdipdi.com  
pdipdi.com



**ABOUT PDI**

PDI helps reduce preventable infections, control healthcare costs, and ultimately help save lives by delivering a broad range of evidence-based, market leading environmental hygiene and patient care solutions. PDI's expertise in making a difference in the community and healthcare environments extends throughout the United States and worldwide. To learn more, visit [www.pdihc.com](http://www.pdihc.com).



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 9480-13	2. EPA Product Manager Eric Miederhoff	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Backspin No-Rinse FCSS	PM # 31	
5. Name and Address of Applicant (Include ZIP Code) Professional Disposables International, Inc. (PDI) 100 Philips Parkway Montvale, NJ 07645  <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Minor Formulation Amendment per PR Notice 98-10 to add alternate inert to CSF; No PRIA fee.

## Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* <b>Certification must be submitted</b>		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Melissa Louis-Juste	Title Regulatory Affairs Associate	Telephone No. (Include Area Code) 201-746-8958	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) 
2. Signature 	3. Title Regulatory Affairs Associate		
5. Typed Name Melissa Louis-Juste	5. Date January 27, 2017		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

October 22, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-510383  
EPA File Symbol or Registration Number: 9480-RG  
Product Name: BACKSPIN NO-RINSE FCSS  
EPA Receipt Date: 21-Oct-2015  
EPA Company Number: 9480  
Company Name: PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.

CHRISTINIA GRIFFIN  
DELTA ANALYTICAL CORP  
PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.  
12510 PROSPERITY DRIVE, SUITE 160  
SILVER SPRING, MD 20904-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6249.

Sincerely,  
*Neresa Downs*  
Front End Processing Staff  
Information Technology & Resources Management Division

# Fee for Service

<sup>975</sup>  
{975899Ä~

This package includes the following

- ☒ New Registration
- ☐ Amendment

- ☒ Studies?      ☐ Fee Waiver?
- ☐ volpay    % Reduction: \_\_\_\_

for Division

- ☒ AD
- ☐ BPPD
- ☐ RD

Risk Mgr. 31

Receipt No.

S-

975899

EPA File Symbol/Reg. No.

9480-RG

Pin-Punch Date:

10/21/2015

☐ This item is NOT subject to FFS action.

## Action Code:

Requested: A 540

Granted: A 540

Amount Due: \$ 5107<sup>00</sup>

## Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: DAVID Leman

Date: 10/22/15

Remarks:





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

October 26, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

DELTA ANALYTICAL CORP  
PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.  
12510 PROSPERITY DRIVE, SUITE 160  
SILVER SPRING, MD 20904

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 21-OCT-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

**Receipt for Section 3**

S: 975899

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Company: 9480 PROFESSIONAL DISPOSABLES INTERNATIONAL

Billable: ☒ Yes ☐ No

Risk Manager: Antimicrobials Division, Risk Management Team 31

Product #: 9480-RG Product Name: BACKSPIN NO-RINSE FCSS

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 20-Oct-2015

OPP Rec'd Date: 21-Oct-2015

Front End Date: 21-Oct-2015

Risk Manager Send Date:

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Application for registration of new product.

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF



October 20, 2015

**49746400**

Document Processing Desk (APPL)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
2777 S. Crystal Drive, Room S-4900  
Arlington VA 22202

Attn: Eric Miederhoff, PM 31

**Re: Application for New Registration: Backspin No-Rinse FCSS**  
**PRIA Fee Category: A540 (receipt attached to application form); Decision time: 5 months; Fee: \$5,107**  
Product is based on the EPA file symbol 9480-RR , Backspray RTU  
**Company: Professional Disposables International, Inc.**  
**Product Name: Backspin No-Rinse FCSS**  
**File Symbol: 9480-**

Dear Mr. Miederhoff:

On behalf of Professional Disposables International, Inc. (PDI), I am submitting an application for a new end-use registration for the product Backspin No-Rinse FCSS (EPA file symbol 9480- ). Certain data requirements are being bridged from Backspray RTU, currently under EPA review to be registered (EPA file symbol 9480-RR).

**PRIA:**

This product is in PRIA Fee Category A540, \$5,107 fee paid in advance (receipt attached to application form), 5 month time frame. This product contains active ingredients and uses included in other EPA registered end use products.

**CSF:**

Backspin No-Rinse FCSS is a sanitizing wipe for hard nonporous food and nonfood contact surfaces. With the exception of the towelette material, the formulation is identical to the Backspray RTU (9480-RR), which is currently being reviewed at EPA.

**Label:**

The Backspin No-Rinse FCSS label is substantially similar to the Backspray RTU (9480-RR) product label. The towelette claims are similar to claims on other EPA approved PDI wipe product labels.

**Chemistry Data**

To support Backspin No-Rinse FCSS, we are citing chemistry data from the Backspray RTU (9480-RR), as well as submitting Part A and Part B chemistry data on the wipe. In conformance with the 810 guidelines, the Part A chemistry data include the wipe characterization assay.

Toxicity Data

To support Backspin No-Rinse FCSS, we are citing toxicity data from the Backspray RTU (9480-RR), currently being reviewed.

Efficacy Data:

To support Backspin No-Rinse FCSS organism claims on the label, we are citing efficacy studies conducted on the Backspray RTU (9480-RR) for those specific claims. In addition, in accordance with EPA's OCSPP 810.2300 guidelines (2012) and EPA's "Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes" (April 12, 2001), PDI is submitting four studies for efficacy testing conducted on the towelette. Also enclosed is one study for testing conducted on the towelette as a non-food contact sanitizer.

Enclosures

The following documents are enclosed in support of this application:

- Transmittal Document
- EPA form 8570-1
- Receipt to show payment of PRIA fee (attached to application)
- Certification with Respect to Citation of Data
- End Use Data Matrix – Internal and External Copies
- Formulator's Exemption Statement
- Confidential Statement of Formula: Basic (2 copies)
- Five copies of label
- Three sets of 7 study volumes listed in attached transmittal

If you have any questions please contact me at [cgriffin@delta-ac.com](mailto:cgriffin@delta-ac.com) or (301) 680-7971.

Sincerely,



Cristina Griffin  
Agent for PDI

cc: Jean Claude Marcelin, PDI

Transmittal Document

Submitter:

Professional Disposables International, Inc. (PDI)  
Two Nice-Pak Park  
Orangeburg, NY 10962-1376

Company Contact:

Cristina Griffin, Delta Analytical Corporation  
Agent for PDI  
12510 Prosperity Drive, Suite 160  
Silver Spring, MD 20904

Regulatory Action in Support of Which this Package is Submitted:

Application for Registration of Backspin No-Rinse FCSS

Submission Date:

October 20, 2015

Submitted Studies:

**49746401** Volume 1: Product Identity, Manufacturing Process, and Enforcement Analytical Method

**49746402** Volume 2: Physical and Chemical Properties

**49746403** Volume 3: PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Staphylococcus aureus* (ATCC 6538) Glass and Rough Plastic- 4ft.<sup>2</sup>

**49746404** Volume 4: PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Escherichia coli* (ATCC 11229) Glass and Rough Plastic- 4ft.<sup>2</sup>

**49746405** Volume 5: PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Shigella boydii* (ATCC 9207) Glass and Rough Plastic- 4ft.<sup>2</sup>

**49746406** Volume 6: PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Listeria monocytogenes* (ATCC 19115) Glass and Rough Plastic- 4ft.<sup>2</sup>

**49746407** Volume 7: Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modified for Pre-Saturated Towelette Product Application): *Enterobacter aerogenes* (ATCC 13048), *Staphylococcus aureus* (ATCC 6538)

## Memorandum

Date: 10/26/15

To: PM 31, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission



October 20, 2015

**49746400**

Document Processing Desk (APPL)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
2777 S. Crystal Drive, Room S-4900  
Arlington VA 22202

Attn: Eric Miederhoff, PM 31

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**Company: Professional Disposables International, Inc.**  
**Product Name: Backspin No-Rinse FCSS**  
**File Symbol: 9480-**

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- Transmittal Document
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- End Use Data Matrix – Internal and External Copies
- Formulator's Exemption Statement
- Confidential Statement of Formula: Basic (2 copies)
- Five copies of label
- Three sets of 7 study volumes listed in attached transmittal

If you have any questions please contact me at [cgriffin@delta-ac.com](mailto:cgriffin@delta-ac.com) or (301) 680-7971.

Sincerely,



Cristina Griffin  
Agent for PDI

cc: Jean Claude Marcelin, PDI



Transmittal Document

Submitter:

Professional Disposables International, Inc. (PDI)  
Two Nice-Pak Park  
Orangeburg, NY 10962-1376

Company Contact:

Cristina Griffin, Delta Analytical Corporation  
Agent for PDI  
12510 Prosperity Drive, Suite 160  
Silver Spring, MD 20904

Regulatory Action in Support of Which this Package is Submitted:

Application for Registration of Backspin No-Rinse FCSS

Submission Date:

October 20, 2015

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# PROCESSING REQUEST

Reg # 9480-13

Decision # 510383

Description: Registration Notice

**Electronic Label & Letter**  
(see PPLS):

OR

**Non Electronic  
Label & Letter**  
(Scanning required):

☒ Dated: 3/11/16

☐ Dated:

\*\*\*Only one label type should be selected\*\*\*

**Other Materials Sent** (see jacket):

☒ New CSF(s) Dated: 10/09/15

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Karen M. Leavy

Division: AD

Phone: 308-6237

Date: 04/12/16



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Antimicrobials Division (7510P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg. Number:

9480-13

Date of Issuance:

4/11/16

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Backspin No-Rinse FCSS

Name and Address of Registrant (include ZIP Code):

Cristina Griffin  
Professional Disposables International, Inc.  
Two Nice-Pak Park  
Orangeburg, NY 10962-1376

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Eric Miederhoff, Product Manager 31  
Regulatory Management Branch I, Antimicrobials Division  
(7510P)

Date:

4/11/16

EPA Form 8570-6

Registration Notice Conditional v.2015a32

2. *Include this text if there is a DCI or EDSP Order; otherwise, delete this section.* You are required to comply with the data requirements described in the DCI or EDSP Order identified below:

- a. ADBAC GDCI-069105-30881
- b. DDAC GDCI 069149-30869

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. *Include the following text if there is no DCI issued for a chemical, but there is a Work Plan or a proposed DCI for that chemical; otherwise, delete this section.* Be aware that proposed data requirements have been identified in a Work Plan or proposed DCI. For more information on these proposed data requirements, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>
4. Make the following label changes before you release the product for shipment:
- Revise the EPA Registration Number to read, "EPA Reg. No. 9480-13."
5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 10/09/2015

2. *Include this text if there is a DCI or EDSP Order; otherwise, delete this section.* You are required to comply with the data requirements described in the DCI or EDSP Order identified below:

- a. ADBAC GDCI-069105-30881
- b. DDAC GDCI 069149-30869

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. *Include the following text if there is no DCI issued for a chemical, but there is a Work Plan or a proposed DCI for that chemical; otherwise, delete this section.* Be aware that proposed data requirements have been identified in a Work Plan or proposed DCI. For more information on these proposed data requirements, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>
4. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 9480-13."
5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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EPA Reg. No. 9480-13  
Decision No. 510383

If you have any questions, please contact Karen M. Leavy by phone at (703)-308-6237, or via email at [Leavy.Karen@epa.gov](mailto:Leavy.Karen@epa.gov).

Enclosure

[Front Panel]

## BACKSPIN NO-RINSE FCSS

**ACCEPTED**

**04/11/2016**

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. **9480-13**

### ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chloride ..... 0.023%

Alkyl (50% C<sub>14</sub>, 40% C<sub>12</sub>, 10% C<sub>16</sub>) dimethyl benzyl ammonium chloride ..... 0.015%

OTHER INGREDIENTS ..... 99.962%

TOTAL ..... 100.000%

**KEEP OUT OF REACH OF CHILDREN**

NET CONTENTS [and/or Net Wt.] \_\_\_\_\_ oz (g) [or lbs. (kg)]  
[Insert number] Cloths [size of each cloth]

[Any Panel]

EPA Reg. No.: 9480-RG

EPA Est. No. : 9480-NY-1 or [EPA Est. No. A=9480-NY-1, C=72956-AR-1 [or others]

*Alpha character will precede batch code on product*

[Manufactured by [or for]]:  
Professional Disposables International, Inc.  
Two Nice-Pak Park, Orangeburg, NY 10962-1376  
[For information call: [phone number to be inserted]]

*[Note to Reviewer: According to EPA's Label Review Manual, Precautionary Statements and First Aid are not required for the registrant to include when the product is classified as Category IV for acute toxicity]*

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## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

### TO SANITIZE [HARD NON POROUS FOOD-CONTACT SURFACES]:

**For Lightly Soiled Surfaces:** Use a [product name] wipe to clean the surface to be treated. Sanitize with additional [product name] wipes. Wipe enough for treated area to remain wet for one [1] minute [or 60 seconds]. Let air dry. No rinsing required.

**For heavily soiled surfaces:** Remove all food particles and soil from surfaces that are to be sanitized by thoroughly washing the surfaces with a detergent, followed by a potable water rinse before applying this [sanitizing wipe] [product name]. Wipe enough for treated area to remain wet for one [1] minute [or 60 seconds]. Let air dry. No rinsing required.

99.999% effective in one [1] minute [or 60 seconds] in the presence of 5% organic soil against *Escherichia coli* [(ATCC # 11229)], *Staphylococcus aureus* [(ATCC #6538)], *Shigella boydii* [(ATCC #9207)], and *Listeria monocytogenes* [(ATCC #19115)].

Items may include: *[Use one or more of the following:]*

[Airline tray tables]	[Fridges]	[Range tops and hoods]
[Appliances]	[High chair trays]	[Reach-in refrigeration and freezer units]
[Backsplashes]	[Hospital meal trays]	[Restaurant tables]
[Bar tops]	[Laminated menus]	[Scales]
[Cafeteria trays]	[Lunch boxes]	[Self-service condiment areas]
[Checkout lanes]	[Microwaves]	[Self-service serviceware areas]
[Condiment containers]	[Mixers]	[Slicers]
[Conveyor belts]	[Nonwood cutting boards]	[Tables]
[Counter tops]	[Nozzles]	[Take out counters]
[Cutting boards]	[Pill counters]	[Waitress stations]
[Dining tables]	[Pill trays]	[Walk-in refrigeration and freezer units]
[Dish racks]	[Probe portion of meat thermometers]	[Work tables]
[Food trays]	[Probe portion of food thermometers]	
[Food carts]	[Ranges]	
[Food preparation tables]		
[Food [manufacturing]		
[processing]		
[equipment][parts]]		

*[The following uses must be preceded by the words: " [outside surface[s] of]" or "[exterior surface[s] of]": ]*

[Beverage dispensers]	[Griddles]	[Steam tables]
[Broilers]	[Grills]	
[Chargrills]	[Ice machines]	[Toasters]
[Cooking surfaces]	[Pulpers]	
[Food mixers]	[Ovens]	

*[Add the following after the list of surfaces:]* and other similar hard, nonporous food contact surfaces.

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**[TO SANITIZE] [HARD NONPOROUS NONFOOD-CONTACT SURFACES]:**

[Cleaning and] Sanitizing Procedure: Use a [product name] wipe to clean the surface to be treated. Sanitize surface with [product name] wipes. Wipe enough for treated area to remain wet for 15 seconds. Let air dry. No rinsing required.

Use one or more of the following:

[bath tubs,]	[employee areas,]	[restaurant chairs]	[telephones,]
[booster seats,]	[garbage cans,]	[shopping carts]	[tiled walls,]
[cash registers,]	[hampers,]	[and/or] [baskets,]	[toilet seats, [and/or]
[chairs,]	[hotel room surfaces]	[showers,]	[rims,]
[cribs,]	[and/or] [counters]	[sinks,]	[towel dispensers,]
[diaper pails]	[infant-changing	[stall doors,]	[vanities,]
[display cabinets,]	tables,]	[store] check-out	[trashcans]
[doorknobs,]	[infant high chairs,]	areas],	
[drain boards,]	[faucets,]	[strollers]	
	[floors,]		

99.9% effective in 15 seconds against *Staphylococcus aureus* (ATCC #6538) and *Enterobacter aerogenes* (ATCC # 13048) [in the presence of organic soil (5% blood serum)].

**[CLEANING AND DEODORIZING]**

Wipe surface with towelette until clean. Let air dry.]

**Dispensing:** [Choose the dispensing directions from below that correspond to the product package.]

[On canister]

Remove lid and discard inner seal. Find center wipe and pull through lid. For optimal use, pull wipes at an angle. When not in use keep lid closed to prevent moisture loss.

[On Flexible Pack or Mobile Pack or Belt Pack]

Peel back label. Pull out wipes as needed. When not in use keep lid closed to prevent moisture loss.

[On Packet]

Tear open packet.

[Pail]

Remove lid and tear open refill package.

[Refill Package]

This refill package is made for use only in a [product name] container; do not use this product in a container for another product. Remove [entire] lid from container. Tear open refill [package] at [notch] [mark] [arrow]. Place [entire] refill package of wipes in empty container. Follow information on container to dispense wipes.

**PRECAUTIONARY STATEMENTS**

Hazards to Humans and Domestic Animals

**Physical or chemical hazard**

Combustible. Do not use or store near heat or open flame.

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## STORAGE AND DISPOSAL

**Storage:** Do not store near heat or open flame. Use product only from original container.

*[For canisters:]*

**Wipe Disposal:** Do not reuse wipe, offer for recycling. If recycling is not available, put in trash collection.

**Canister Disposal:** Do not reuse this container. Rinse and recycle. If recycling is not available, put in trash.

*[For flexible packs, mobile packs, belt packs or single packets:]*

**Wipe Disposal:** Do not reuse wipe, offer for recycling. If recycling is not available, put in trash collection.

**Flexpack Disposal:** Put empty package in trash collection.

*[For pail:]*

**Wipe Disposal:** Do not reuse wipe, offer for recycling. If recycling is not available, put in trash collection.

**Packaging Disposal:** Put empty package in trash collection.

**Pail Disposal:** Do not reuse this container. Rinse and recycle. If recycling is not available, put in trash.

*[Use at least one of the use sites indicated in the paragraph below or in the "For Use In" section below:]*

### [AREAS OF USE IN FOOD SERVICE AND FOOD PREPARATION:]

This product is recommended for use in retail food establishments [including:] [restaurants,] [hotels,] [kitchens,] [airplanes,] [food service in healthcare settings,] [delicatessens,] [supermarkets,] [temporary food establishments], [food processing plants,] and other food service and food preparation settings where the [control of the hazards] [prevention] of cross-contamination between treated surfaces is of primary importance.

### [FOR USE IN:]

[Airplanes]	[Food Processing Facilities]	[Mortuaries]
[Athletic facilities]	[Food Service Facilities]	[Motels]
[Banquet halls]	[Food Trucks]	[Nurseries]
[Beverage Processing Facilities]	[Funeral homes]	[Nursing Homes]
[Cafeterias]	[Gyms]	[Nutraceutical Production Facilities]
[Cars]	[Grocery]	[Pharmaceutical Production Facilities]
[Caterers]	[Healthcare Food Service]	[Pharmacy]
[Catering facilities]	[Health clubs]	[Poultry/Meat/Seafood Packing Facilities]
[Correctional facilities]	[Homes residences]	[Restaurants]
[Cruise Ships]	[Hotels]	[Schools]
[Day Care Settings]	[Households]	[Shopping centers]
[Delicatessens]	[Household kitchens and/or bathrooms]	[Temporary Food Establishments]
[Dining halls]	[In-Store Demos]	[Transportation Centers]
[Drug Stores]	[Kitchens]	
[Food Manufacturing Facilities]	[Mobil Food Establishments]	
[Food Packaging Facilities]		

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**[For use on the following[:] [types of surfaces:]]**

[Aluminum]  
[Chrome]  
[Corian®]  
[Finished Wood]  
[Finished Polyurethane]  
[Formica®]  
[Glazed Porcelain (Surfaces)]  
[Glazed Porcelain (Enamel)(Kitchen)(Tile)]  
[Laminated Surfaces (Laminate)]  
[Laminated Wood]  
[Metal]  
[Polystyrene]  
[Quartz]  
[Sealed Cement]  
[Sealed Granite]  
[Sealed Synthetic Marble]  
[Steel Surfaces]  
[Sealed Stone Surfaces]  
[Stainless Steel]

**Optional Label Claims**

*[All below are optional/ label (placement optional) literature and promotional statements]*

\*99.999% effective in 60 seconds against *Staphylococcus aureus* [(ATCC #6538)], *Escherichia coli* [(ATCC #11229)], *Shigella boydii* [(ATCC# 9207)], and *Listeria monocytogenes* [(ATCC# 19115)] on hard, nonporous food contact surfaces.

X ct. X *[to be replaced with unit packet count]*

Aids in the reduction of cross-contamination between treated surfaces. \*\*

All applicable health inspection agency code requirements must be followed for cleaning, rinsing and sanitizing.

Always follow directions for use on this [or the] label.

A convenient way to clean and sanitize

An efficient way to clean and sanitize

Antibacterial

Antimicrobial

Antimicrobial wipes

Bleach-free *[this is included as useful info for users needing a bleach-free product]*

By Grime Boss®

Cleans, deodorizes and kills common foodservice[foodborne] bacteria

Cleans, deodorizes and kills common household bacteria

Commercial use

Convenient wipes

Convenient way to sanitize. One wipe at a time.

*[for use on canisters, not packets]* Cost Savings: Our *[product name]* wipe is [X] times larger and [X]% less expensive than [PDI's or our [previous]] individually packed wipes. The easy grip canister contains [X] more wipes and creates less waste than individual packets. Now you can do more with less waste!

Designed and formulated for use on large hard nonporous surface areas *[list surfaces from approved list]*

Designed to be effective on large hard nonporous surfaces *[including: [list surfaces from approved list]*

Designed to clean, then sanitize lightly soiled, hard, nonporous food contact surfaces *[where the control of cross-contamination between treated surfaces is of primary importance]*

Do not use on natural marble, windows, unpainted wood, brass, clear plastic or colored grout.

Each *[or Every]* wipe releases the right amount of sanitizer

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Easy sanitizing on the go  
 Easy sanitizing for hard nonporous surfaces around the house [office] [bathroom] [kitchen]  
 Easy to use  
 Effective in sanitizing your hard nonporous surfaces [kitchen] [bathroom] surfaces  
 Eliminates odors  
 Every day use  
 Extra large wipes  
 Fast drying formulation  
 Fits with Swiffer sweepers  
 Food Code Compliant [referencing 2013 Food Code]  
 Food contact surface\*\* sanitizing wipe  
 Food processing [commercial] [industrial] use  
 For hard nonporous household surfaces  
 For your [heavy] [or light] duty jobs  
 For cleaning on the go  
 For use in food processing facilities where dry cleaning is [critical [required] [for] [to] your operation] [*dry cleaning is a method of cleaning where it is necessary to keep water content at a minimum*]  
 For use in retail and institutional food establishments, food processing plants and other health department regulated food facilities. \*\*  
 For use on hard nonporous surfaces in [professional][commercial] kitchens  
 Incorporate as part of your [pathogen reduction] [or food safety] program  
 Ideal for Daily Use  
 Ideal for water-sensitive equipment  
 Industrial use [*only for use in products labeled for commercial uses*]  
 Helps prevent cross-contamination [by killing bacteria on the treated surface and on the wipe. \*\*]  
 [its] [Product name's] quat-based formula is [EPA] registered  
 Kills 99.9% of *Staphylococcus aureus* [(ATCC #6538)] and *Enterobacter aerogenes* [(ATCC # 13048)] in 15 seconds [on hard, nonporous non food contact surfaces]  
 Kills 99.999% of *Staphylococcus aureus* [(ATCC #6538)], *Escherichia coli* [(ATCC #11229)], *Shigella boydii* [(ATCC# 9207)], and *Listeria monocytogenes* [(ATCC# 19115)] in 60 seconds on [cleaned] [and rinsed] hard, nonporous food contact surfaces  
 Kills 99.999% of *Listeria monocytogenes* [(ATCC# 19115)] on hard, nonporous food contact surfaces  
 Kills 99.999% of common foodborne pathogens  
 Kills bacteria on the wipe and on the surface  
 Kills [99.9% of] common household bacteria  
 Kills common household bacteria including: [*Staphylococcus aureus*] [Staph], [*Escherichia coli*] [E. coli], [*Shigella boydii*] [Shigella], and *Listeria monocytogenes* [Listeria]  
 Kills common foodborne pathogens including: [*Staphylococcus aureus*] [Staph], [*Escherichia coli*] [E. coli], [*Shigella boydii*] [Shigella], and *Listeria monocytogenes* [Listeria]  
 Kitchen surface wipes  
 Large enough to work with sweepers  
 Large enough to work with Grime Boss® Sweepers  
 Leaves no harsh chemical residue  
 Less waste than individually wrapped wipes  
 [Moisture] [Hydro-] lock lid  
 [Made in USA] [of Domestic and [Foreign]][Imported] Materials] [Made in [*insert country*]]

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[Neutralizes] [Eliminates] odors No animal ingredients  
 No mixing or measuring required  
 [No mixing, no measuring, no problem]  
 Noncorrosive formulation  
 No-Rinse Sanitizer  
 Only for commercial uses  
 Premeasured, premoistened sanitizing wipes for use on hard nonporous surfaces.  
 [Product name] are a convenient method for sanitizing thermometers and other small wares  
 [Product name] can be part of your facilities' [Hazard Analysis Critical Control Point] [HACCP] plan.  
 [Product name], food contact sanitizing wipe formulated and designed to clean and sanitize [insert food contact surfaces].  
 Proven effective against foodborne pathogens listed below\*  
 \*99.999% effective in 60 seconds against *Staphylococcus aureus* [(ATCC #6538)], *Escherichia coli* [(ATCC #11229)], *Shigella boydii* [(ATCC# 9207)], and *Listeria monocytogenes* [(ATCC# 19115)] on hard, nonporous food contact surfaces.  
 Quick and easy sanitizing of [add use surfaces from this label]  
 Ready to use  
 Recommended for use on hard, nonporous nonfood contact surfaces as a sanitizer  
 Sanitizes food prep surfaces  
 Sanitizes [baby][children's] [booster chairs] [high chair trays] [strollers]  
 Sanitizes hard nonporous surfaces  
 Sanitizes interiors of [microwave ovens], [refrigerators], [stoves], [freezers], [food trays], [lunch boxes], [dishwashers], [dish racks], [sinks]  
 Sanitizing Wipe  
 Saves time  
 Say good-bye to dirty rags and buckets  
 Simply pull, wipe, and toss [to help reduce the risk of cross-contamination between treated surfaces] [!]  
 Streak-free cleaning  
 Strong wipe for tough jobs  
 Test in an inconspicuous area prior to use  
 The [Product name] formula is noncorrosive. [Compatible with] [or May be used on] [or Will not damage]: [Stainless steel] [and/or] [Small] [commercial kitchen wares]  
 The [X wipe size] of [product name] is large enough to use effectively on a variety of small wares and equipment of busy commercial kitchens. The [new] easy grip canister contains [count] wipes and creates less waste than individual packets. [product name]: Now you can do more with less waste!  
 The bacteria are killed in 60 seconds by contact with the liquid in the wipe. The product is effective when the surface is completely contacted with the wipe.  
 The fast, easy and effective way to sanitize hard, nonporous [food contact] [and] [nonfood contact] surfaces  
 The wet wipe for dry cleaning [dry cleaning is a method of cleaning where it is necessary to keep water content at a minimum]  
 The wipe is effective against all hard, nonporous surface areas to which all liquid has been imparted for the required contact time  
 [Trial] [Value] size  
 Use [as a part of] [in support of] your [FSMA-driven/compliant] HACCP plan  
 Use in conjunction with Sani Professional QuatCheck Kit to verify active level for your Health [Inspection authority] [Inspector]  
 Use on hard nonporous surfaces wherever [sanitizing] is important  
 Use to sanitize hard nonporous surfaces during in-store food [demos] [or demonstrations]  
 Use to sanitize the probe portion of [food] [and] meat thermometers.  
 Use with [patent pending] [proprietary] [Triple Take Dispenser] [Belt Packs] [Wall Brackets]  
 User friendly

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Uses X% less plastic than similar count canisters

Versatile: The [wipe size] [Product name] size is ideal for use on thermometers, meat probes, steam wands, and small ware equipment.

Where compliance and guest experience meet

---

6-Month Advertising Claims [product in marketplace 6 months]

[Note: The following claims will be used as this product replaces a current PDI EPA registered product:]

[Use in place of] [replaces]: [previous product names]

Formerly marketed as [previous product names]

Our fastest drying formulation yet

New! Kills Listeria\* \*99.999% of *Listeria monocytogenes* in 60 seconds.

Now! Kills 99.999% of *Listeria monocytogenes* [on hard, nonporous food contact surfaces]

Table Turners has a new look

Thermosan has a new look

Sani-Wipe has a new look

[\*\* hard nonporous surfaces only]

[Graphics depicting use sites listed on this label can appear on product label and labeling.]

[The following graphics and statements are optional.

They may be placed anywhere on label/container.]

**NOT FOR USE ON SKIN**

**FOR USE ON HARD NONPOROUS SURFACES ONLY**



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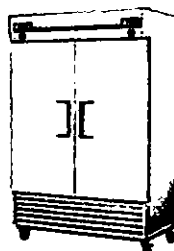
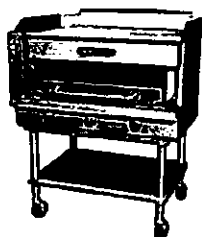
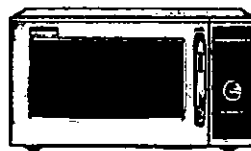
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# **THERMO-SAN™**

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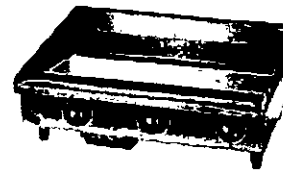
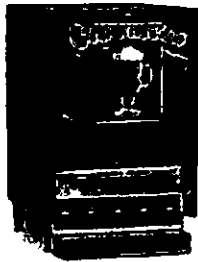
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**PET**



**HDPE**

[The following are company logos for use on PDI product labels. The purpose of the logo is for easy recognition of PDI products in the marketplace.]



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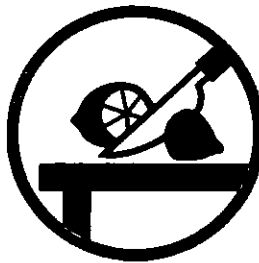
Page 10 of 15



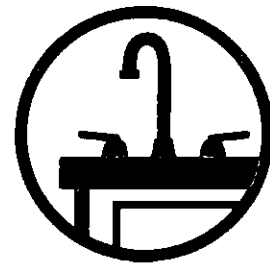
Dining Tables



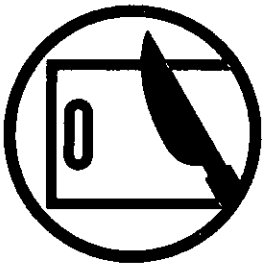
Food Preparation Tables



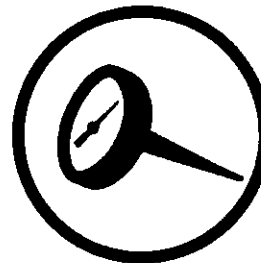
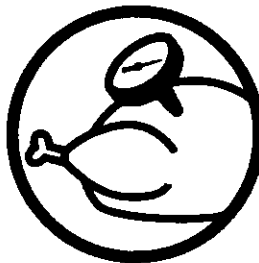
Counter Tops



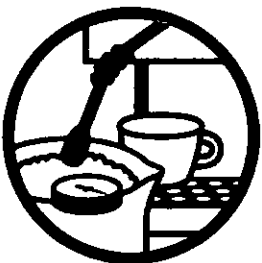
Non-wood Cutting Boards



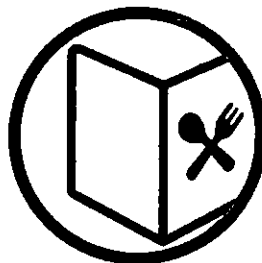
Probe Portion of Meat Thermometer



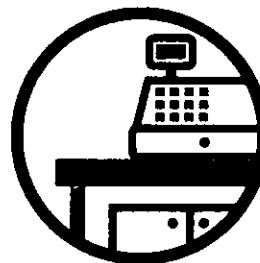
Thermometers,  
Steam Wands



Laminated Menus



Counters



Cafeteria Trays,  
Hospital Meal Trays  
Airline Tray Tables  
Pill Trays



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Bar Tops



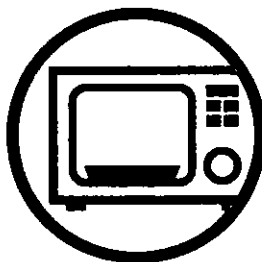
Waitress Stations



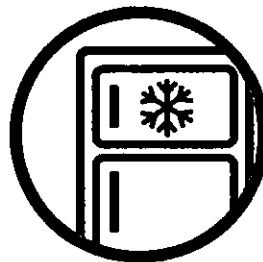
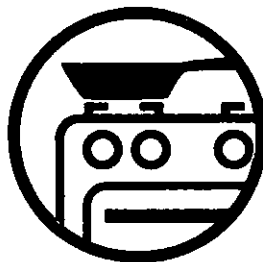
Food Carts



Microwaves, Ranges



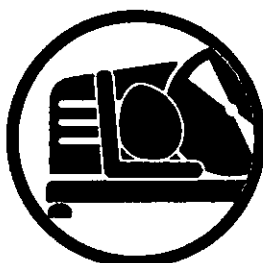
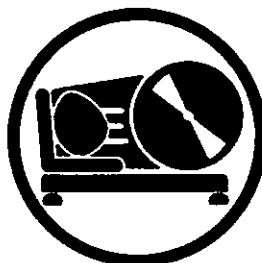
Refrigeration, Freezer Units



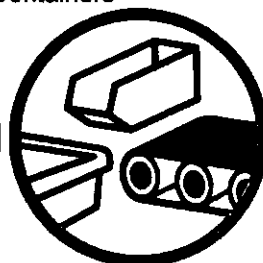
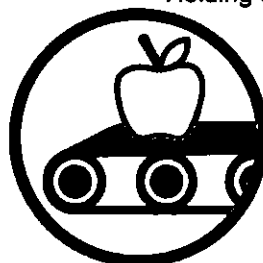
Self-Service Condiment  
Areas, Condiment Containers



Deli Slicer



Conveyor Belts,  
Conveyor Lines,  
Hopper Trays,  
Holding Containers



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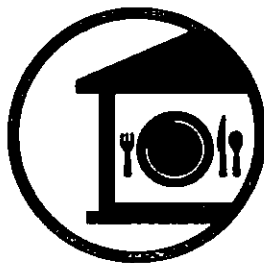
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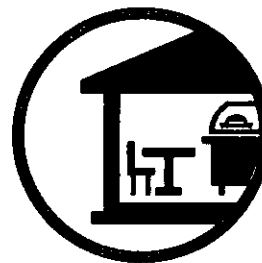
Small Wares  
(beverage dispensers,  
food mixers, scales)



Restaurants  
Foodservice



Dining Halls/Cafeterias



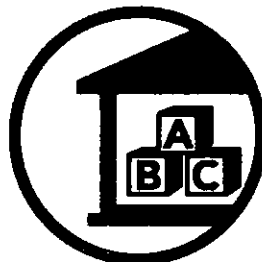
Airplanes/Airports



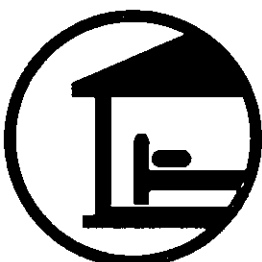
Caterers



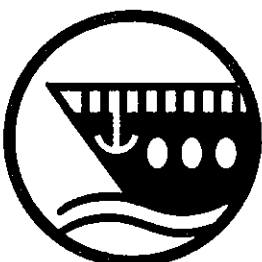
Daycare Settings



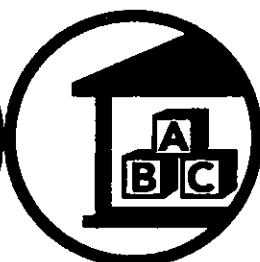
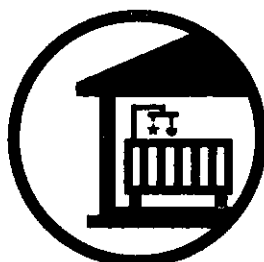
Hotels/Motels



Cruise Ships



Nurseries



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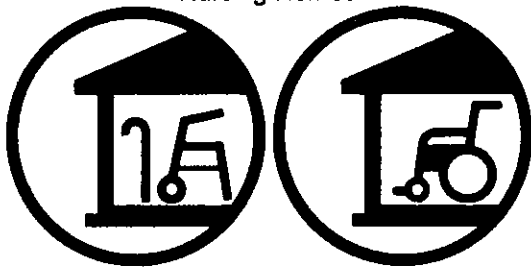
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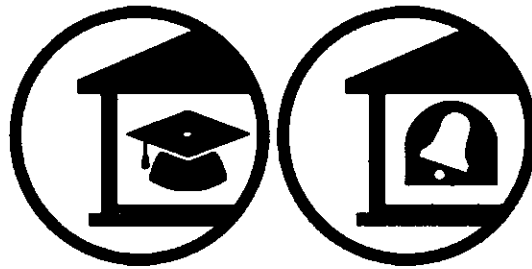
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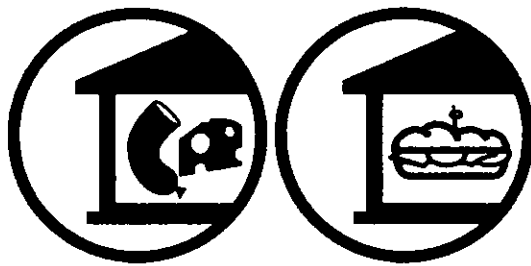
Nursing Homes



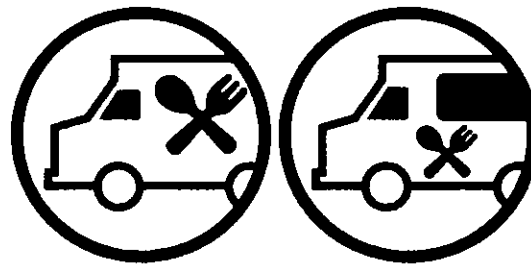
Schools



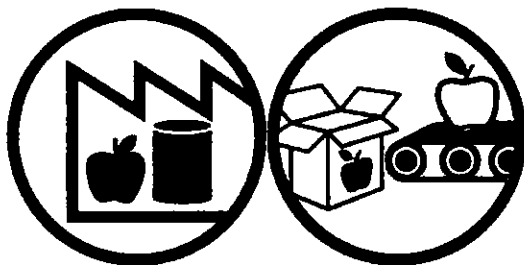
Delicatessens



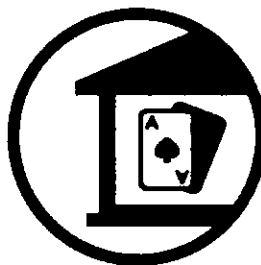
Food Trucks



Food Manufacturing Facilities



Casinos



Grocery



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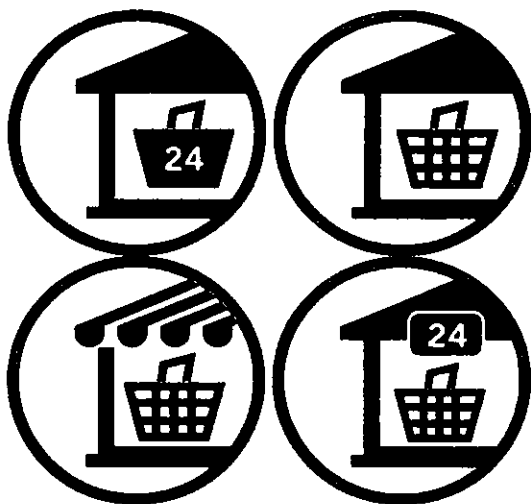
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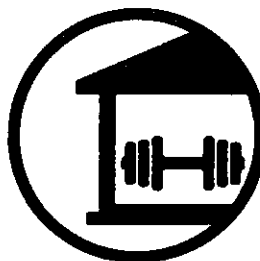
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Convenience Stores



Fitness



Kills Listeria in 60 seconds



Kills Listeria in 1 minute



[Logo]



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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Antimicrobials Division (7510P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg. Number:

9480-13

Date of Issuance:

4/11/16

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Backspin No-Rinse FCSS

Name and Address of Registrant (include ZIP Code):

Cristina Griffin  
Professional Disposables International, Inc.  
Two Nice-Pak Park  
Orangeburg, NY 10962-1376

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Eric Miederhoff, Product Manager 31  
Regulatory Management Branch I, Antimicrobials Division  
(7510P)

Date:

4/11/16

2. *Include this text if there is a DCI or EDSP Order; otherwise, delete this section.* You are required to comply with the data requirements described in the DCI or EDSP Order identified below:

- a. ADBAC GDCI-069105-30881
- b. DDAC GDCI 069149-30869

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. *Include the following text if there is no DCI issued for a chemical, but there is a Work Plan or a proposed DCI for that chemical; otherwise, delete this section.* Be aware that proposed data requirements have been identified in a Work Plan or proposed DCI. For more information on these proposed data requirements, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>
4. Make the following label changes before you release the product for shipment:
- Revise the EPA Registration Number to read, "EPA Reg. No. 9480-13."
5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 10/09/2015

Page 3 of 3  
EPA Reg. No. 9480-13  
Decision No. 510383

If you have any questions, please contact Karen M. Leavy by phone at (703)-308-6237, or via email at [Leavy.Karen@epa.gov](mailto:Leavy.Karen@epa.gov).

Enclosure



[Front Panel]

## BACKSPIN NO-RINSE FCSS

**ACCEPTED**

**04/11/2016**

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. **9480-13**

### ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chloride .....	0.023%
Alkyl (50% C <sub>14</sub> , 40% C <sub>12</sub> , 10% C <sub>16</sub> ) dimethyl benzyl ammonium chloride .....	0.015%
OTHER INGREDIENTS .....	99.962%
TOTAL .....	100.000%

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS [and/or Net Wt.] \_\_\_\_\_ oz (g) [or lbs. (kg)]  
[Insert number] Cloths [size of each cloth]

[Any Panel]

EPA Reg. No.: 9480-RG

EPA Est. No. : 9480-NY-1 or [EPA Est. No. A=9480-NY-1, C=72956-AR-1 [or others]

*Alpha character will precede batch code on product*

[Manufactured by [or for]]:  
Professional Disposables International, Inc.  
Two Nice-Pak Park, Orangeburg, NY 10962-1376  
[For information call: [phone number to be inserted]]

*[Note to Reviewer: According to EPA's Label Review Manual, Precautionary Statements and First Aid are not required for the registrant to include when the product is classified as Category IV for acute toxicity]*

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## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

### TO SANITIZE [HARD NON POROUS FOOD-CONTACT SURFACES]:

**For Lightly Soiled Surfaces:** Use a [product name] wipe to clean the surface to be treated. Sanitize with additional [product name] wipes. Wipe enough for treated area to remain wet for one [1] minute [or 60 seconds]. Let air dry. No rinsing required.

**For heavily soiled surfaces:** Remove all food particles and soil from surfaces that are to be sanitized by thoroughly washing the surfaces with a detergent, followed by a potable water rinse before applying this [sanitizing wipe] [product name]. Wipe enough for treated area to remain wet for one [1] minute [or 60 seconds]. Let air dry. No rinsing required.

99.999% effective in one [1] minute [or 60 seconds] in the presence of 5% organic soil against *Escherichia coli* [(ATCC # 11229)], *Staphylococcus aureus* [(ATCC #6538)], *Shigella boydii* [(ATCC #9207)], and *Listeria monocytogenes* [(ATCC #19115)].

Items may include: [Use one or more of the following:]

[Airline tray tables]	[Fridges]	[Range tops and hoods]
[Appliances]	[High chair trays]	[Reach-in refrigeration and freezer units]
[Backsplashes]	[Hospital meal trays]	[Restaurant tables]
[Bar tops]	[Laminated menus]	[Scales]
[Cafeteria trays]	[Lunch boxes]	[Self-service condiment areas]
[Checkout lanes]	[Microwaves]	[Self-service serviceware areas]
[Condiment containers]	[Mixers]	[Slicers]
[Conveyer belts]	[Nonwood cutting boards]	[Tables]
[Counter tops]	[Nozzles]	[Take out counters]
[Cutting boards]	[Pill counters]	[Waitress stations]
[Dining tables]	[Pill trays]	[Walk-in refrigeration and freezer units]
[Dish racks]	[Probe portion of meat thermometers]	[Work tables]
[Food trays]	[Probe portion of food thermometers]	
[Food carts]	[Ranges]	
[Food preparation tables]		
[Food [manufacturing]		
[processing]		
[equipment][parts]]		

[The following uses must be preceded by the words: " [outside surface(s) of]" or "[exterior surface(s) of]": ]

[Beverage dispensers]	[Griddles]	[Steam tables]
[Broilers]	[Grills]	
[Chargrills]	[Ice machines]	[Toasters]
[Cooking surfaces]	[Pulpers]	
[Food mixers]	[Ovens]	

[Add the following after the list of surfaces:] and other similar hard, nonporous food contact surfaces.

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**[TO SANITIZE] [HARD NONPOROUS NONFOOD-CONTACT SURFACES]:**

[Cleaning and] Sanitizing Procedure: Use a [product name] wipe to clean the surface to be treated. Sanitize surface with [product name] wipes. Wipe enough for treated area to remain wet for 15 seconds. Let air dry. No rinsing required.

Use one or more of the following:

[bath tubs,]	[employee areas,]	[restaurant chairs]	[telephones,]
[booster seats,]	[garbage cans,]	[shopping carts]	[tiled walls,]
[cash registers,]	[hampers,]	[and/or] [baskets,]	[toilet seats, [and/or]
[chairs,]	[hotel room surfaces]	[showers,]	[rims,]
[cribs,]	[and/or] [counters]	[sinks,]	[towel dispensers,]
[diaper pails]	[infant-changing	[stall doors,]	[vanities,]
[display cabinets,]	tables,]	[store] check-out	[trashcans]
[doorknobs,]	[infant high chairs,]	areas,	
[drain boards,]	[faucets,]	[strollers]	
	[floors,]		

99.9% effective in 15 seconds against *Staphylococcus aureus* (ATCC #6538) and *Enterobacter aerogenes* (ATCC # 13048) [in the presence of organic soil (5% blood serum)].

**[CLEANING AND DEODORIZING]**

Wipe surface with towelette until clean. Let air dry.]

**Dispensing:** [Choose the dispensing directions from below that correspond to the product package.]

[On canister]

Remove lid and discard inner seal. Find center wipe and pull through lid. For optimal use, pull wipes at an angle. When not in use keep lid closed to prevent moisture loss.

[On Flexible Pack or Mobile Pack or Belt Pack]

Peel back label. Pull out wipes as needed. When not in use keep lid closed to prevent moisture loss.

[On Packet]

Tear open packet.

[Pail]

Remove lid and tear open refill package.

[Refill Package]

This refill package is made for use only in a [product name] container; do not use this product in a container for another product. Remove [entire] lid from container. Tear open refill [package] at [notch] [mark] [arrow]. Place [entire] refill package of wipes in empty container. Follow information on container to dispense wipes.

**PRECAUTIONARY STATEMENTS**

Hazards to Humans and Domestic Animals

**Physical or chemical hazard**

Combustible. Do not use or store near heat or open flame.

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## STORAGE AND DISPOSAL

**Storage:** Do not store near heat or open flame. Use product only from original container.

*[For canisters:]*

**Wipe Disposal:** Do not reuse wipe, offer for recycling. If recycling is not available, put in trash collection.

**Canister Disposal:** Do not reuse this container. Rinse and recycle. If recycling is not available, put in trash.

*[For flexible packs, mobile packs, belt packs or single packets:]*

**Wipe Disposal:** Do not reuse wipe, offer for recycling. If recycling is not available, put in trash collection.

**Flexpack Disposal:** Put empty package in trash collection.

*[For pail:]*

**Wipe Disposal:** Do not reuse wipe, offer for recycling. If recycling is not available, put in trash collection.

**Packaging Disposal:** Put empty package in trash collection.

**Pail Disposal:** Do not reuse this container. Rinse and recycle. If recycling is not available, put in trash.

*[Use at least one of the use sites indicated in the paragraph below or in the "For Use In" section below:]*

### [AREAS OF USE IN FOOD SERVICE AND FOOD PREPARATION:]

This product is recommended for use in retail food establishments [including:] [restaurants,] [hotels,] [kitchens,] [airplanes,] [food service in healthcare settings,] [delicatessens,] [supermarkets,] [temporary food establishments], [food processing plants,] and other food service and food preparation settings where the [control of the hazards] [prevention] of cross-contamination between treated surfaces is of primary importance.

### [FOR USE IN:]

[Airplanes]	[Food Processing Facilities]	[Mortuaries]
[Athletic facilities]	[Food Service Facilities]	[Motels]
[Banquet halls]	[Food Trucks]	[Nurseries]
[Beverage Processing Facilities]	[Funeral homes]	[Nursing Homes]
[Cafeterias]	[Gyms]	[Nutraceutical Production Facilities]
[Cars]	[Grocery]	[Pharmaceutical Production Facilities]
[Caterers]	[Healthcare Food Service]	[Pharmacy]
[Catering facilities]	[Health clubs]	[Poultry/Meat/Seafood Packing Facilities]
[Correctional facilities]	[Homes residences]	[Restaurants]
[Cruise Ships]	[Hotels]	[Schools]
[Day Care Settings]	[Households]	[Shopping centers]
[Delicatessens]	[Household kitchens and/or bathrooms]	[Temporary Food Establishments]
[Dining halls]	[In-Store Demos]	[Transportation Centers]
[Drug Stores]	[Kitchens]	
[Food Manufacturing Facilities]	[Mobil Food Establishments]	
[Food Packaging Facilities]		

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**[For use on the following:] [types of surfaces:]**

[Aluminum]  
[Chrome]  
[Corian®]  
[Finished Wood]  
[Finished Polyurethane]  
[Formica®]  
[Glazed Porcelain (Surfaces)]  
[Glazed Porcelain (Enamel)(Kitchen)(Tile)]  
[Laminated Surfaces (Laminate)]  
[Laminated Wood]  
[Metal]  
[Polystyrene]  
[Quartz]  
[Sealed Cement]  
[Sealed Granite]  
[Sealed Synthetic Marble]  
[Steel Surfaces]  
[Sealed Stone Surfaces]  
[Stainless Steel]

**Optional Label Claims**

*[All below are optional/ label (placement optional) literature and promotional statements]*

\*99.999% effective in 60 seconds against *Staphylococcus aureus* [(ATCC #6538)], *Escherichia coli* [(ATCC #11229)], *Shigella boydii* [(ATCC# 9207)], and *Listeria monocytogenes* [(ATCC# 19115)] on hard, nonporous food contact surfaces.

X ct. X *[to be replaced with unit packet count]*

Aids in the reduction of cross-contamination between treated surfaces. \*\*

All applicable health inspection agency code requirements must be followed for cleaning, rinsing and sanitizing.

Always follow directions for use on this [or the] label.

A convenient way to clean and sanitize

An efficient way to clean and sanitize

Antibacterial

Antimicrobial

Antimicrobial wipes

Bleach-free *[this is included as useful info for users needing a bleach-free product]*

By Grime Boss®

Cleans, deodorizes and kills common foodservice[foodborne] bacteria

Cleans, deodorizes and kills common household bacteria

Commercial use

Convenient wipes

Convenient way to sanitize. One wipe at a time.

*[for use on canisters, not packets]* Cost Savings: Our *[product name]* wipe is [X] times larger and [X]% less expensive than [PDI's or our (previous)] individually packed wipes. The easy grip canister contains [X] more wipes and creates less waste than individual packets. Now you can do more with less waste!

Designed and formulated for use on large hard nonporous surface areas *[list surfaces from approved list]*

Designed to be effective on large hard nonporous surfaces [including]: *[list surfaces from approved list]*

Designed to clean, then sanitize lightly soiled, hard, nonporous food contact surfaces [where the control of cross-contamination between treated surfaces is of primary importance]

Do not use on natural marble, windows, unpainted wood, brass, clear plastic or colored grout.

Each [or Every] wipe releases the right amount of sanitizer

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Easy sanitizing on the go  
 Easy sanitizing for hard nonporous surfaces around the house [office] [bathroom] [kitchen]  
 Easy to use  
 Effective in sanitizing your hard nonporous surfaces [kitchen] [bathroom] surfaces  
 Eliminates odors  
 Every day use  
 Extra large wipes  
 Fast drying formulation  
 Fits with Swiffer sweepers  
 Food Code Compliant [referencing 2013 Food Code]  
 Food contact surface\*\* sanitizing wipe  
 Food processing [commercial] [industrial] use  
 For hard nonporous household surfaces  
 For your [heavy] [or light] duty jobs  
 For cleaning on the go  
 For use in food processing facilities where dry cleaning is [critical [required] [for] [to] your operation] [*dry cleaning is a method of cleaning where it is necessary to keep water content at a minimum*]  
 For use in retail and institutional food establishments, food processing plants and other health department regulated food facilities. \*\*  
 For use on hard nonporous surfaces in [professional][commercial] kitchens  
 Incorporate as part of your [pathogen reduction] [or food safety] program  
 Ideal for Daily Use  
 Ideal for water-sensitive equipment  
 Industrial use [*only for use in products labeled for commercial uses*]  
 Helps prevent cross-contamination [by killing bacteria on the treated surface and on the wipe. \*\*]  
 [Its] [Product name's] quat-based formula is [EPA] registered  
 Kills 99.9% of *Staphylococcus aureus* [(ATCC #6538)] and *Enterobacter aerogenes* [(ATCC # 13048)] in 15 seconds [on hard, nonporous non food contact surfaces]  
 Kills 99.999% of *Staphylococcus aureus* [(ATCC #6538)], *Escherichia coli* [(ATCC #11229)], *Shigella boydii* [(ATCC# 9207)], and *Listeria monocytogenes* [(ATCC# 19115)] in 60 seconds on [cleaned] [and rinsed] hard, nonporous food contact surfaces  
 Kills 99.999% of *Listeria monocytogenes* [(ATCC# 19115)] on hard, nonporous food contact surfaces  
 Kills 99.999% of common foodborne pathogens  
 Kills bacteria on the wipe and on the surface  
 Kills [99.9% of] common household bacteria  
 Kills common household bacteria including: [*Staphylococcus aureus*] [Staph], [*Escherichia coli*] [E. coli], [*Shigella boydii*] [Shigella], and *Listeria monocytogenes* [Listeria]  
 Kills common foodborne pathogens including: [*Staphylococcus aureus*] [Staph], [*Escherichia coli*] [E. coli], [*Shigella boydii*] [Shigella], and *Listeria monocytogenes* [Listeria]  
 Kitchen surface wipes  
 Large enough to work with sweepers  
 Large enough to work with Grime Boss® Sweepers  
 Leaves no harsh chemical residue  
 Less waste than individually wrapped wipes  
 [Moisture] [Hydro-] lock lid  
 [Made in USA] [of Domestic and [Foreign]][Imported] Materials] [Made in [*insert country*]]

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[Neutralizes] [Eliminates] odors No  
 animal ingredients  
 No mixing or measuring required  
 [No mixing, no measuring, no problem]  
 Noncorrosive formulation  
 No-Rinse Sanitizer  
 Only for commercial uses  
 Premeasured, premoistened sanitizing wipes for use on hard nonporous surfaces.  
 [Product name] are a convenient method for sanitizing thermometers and other small wares  
 [Product name] can be part of your facilities' [Hazard Analysis Critical Control Point] [HACCP] plan.  
 [Product name], food contact sanitizing wipe formulated and designed to clean and sanitize [insert food  
 contact surfaces].  
 Proven effective against foodborne pathogens listed below\*  
 \*99.999% effective in 60 seconds against *Staphylococcus aureus* [(ATCC  
 #6538)], *Escherichia coli* [(ATCC #11229)], *Shigella boydii* [(ATCC# 9207)], and *Listeria monocytogenes*  
 [(ATCC# 19115)] on hard, nonporous food contact surfaces.  
 Quick and easy sanitizing of [add use surfaces from this label]  
 Ready to use  
 Recommended for use on hard, nonporous nonfood contact surfaces as a sanitizer  
 Sanitizes food prep surfaces  
 Sanitizes [baby][children's] [booster chairs] [high chair trays] [strollers]  
 Sanitizes hard nonporous surfaces  
 Sanitizes interiors of [microwave ovens], [refrigerators], [stoves], [freezers], [food trays], [lunch boxes],  
 [dishwashers], [dish racks], [sinks]  
 Sanitizing Wipe  
 Saves time  
 Say good-bye to dirty rags and buckets  
 Simply pull, wipe, and toss [to help reduce the risk of cross-contamination between treated surfaces] [!]  
 Streak-free cleaning  
 Strong wipe for tough jobs  
 Test in an inconspicuous area prior to use  
 The [Product name] formula is noncorrosive. [Compatible with] [or May be used on] [or Will not damage]:  
 [Stainless steel] [and/or] [Small] [commercial kitchen wares]  
 The [X wipe size] of [product name] is large enough to use effectively on a variety of small wares and  
 equipment of busy commercial kitchens. The [new] easy grip canister contains [count] wipes and  
 creates less waste than individual packets. [product name]: Now you can do more with less waste!  
 The bacteria are killed in 60 seconds by contact with the liquid in the wipe. The product is effective when  
 the surface is completely contacted with the wipe.  
 The fast, easy and effective way to sanitize hard, nonporous [food contact] [and] [nonfood contact]  
 surfaces  
 The wet wipe for dry cleaning [dry cleaning is a method of cleaning where it is necessary to keep water  
 content at a minimum]  
 The wipe is effective against all hard, nonporous surface areas to which all liquid has been imparted for the  
 required contact time  
 [Trial] [Value] size  
 Use [as a part of] [in support of] your [FSMA-driven/compliant] HACCP plan  
 Use in conjunction with Sani Professional QuatCheck Kit to verify active level for your Health [Inspection  
 authority] [Inspector]  
 Use on hard nonporous surfaces wherever [sanitizing] is important  
 Use to sanitize hard nonporous surfaces during in-store food [demos] [or demonstrations]  
 Use to sanitize the probe portion of [food] [and] meat thermometers.  
 Use with [patent pending] [proprietary] [Triple Take Dispenser] [Belt Packs] [Wall Brackets]  
 User friendly

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Uses X% less plastic than similar count canisters

Versatile: The [wipe size] [Product name] size is ideal for use on thermometers, meat probes, steam wands, and small ware equipment.

Where compliance and guest experience meet

---

**6-Month Advertising Claims [product in marketplace 6 months]**

[Note: The following claims will be used as this product replaces a current PDI EPA registered product:]

[Use in place of] [replaces]: [previous product names]

Formerly marketed as [previous product names]

Our fastest drying formulation yet

New! Kills Listeria\* \*\*99.999% of *Listeria monocytogenes* in 60 seconds.

Now! Kills 99.999% of *Listeria monocytogenes* [on hard, nonporous food contact surfaces]

Table Turners has a new look

Thermosan has a new look

Sani-Wipe has a new look

[\*\* hard nonporous surfaces only]

[Graphics depicting use sites listed on this label can appear on product label and labeling.]

[The following graphics and statements are optional.

They may be placed anywhere on label/container.]

**NOT FOR USE ON SKIN**

**FOR USE ON HARD NONPOROUS SURFACES ONLY**



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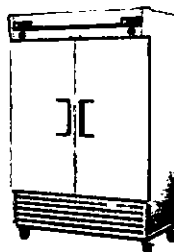
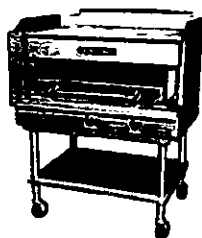
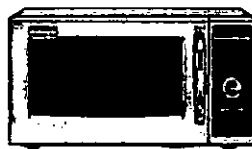
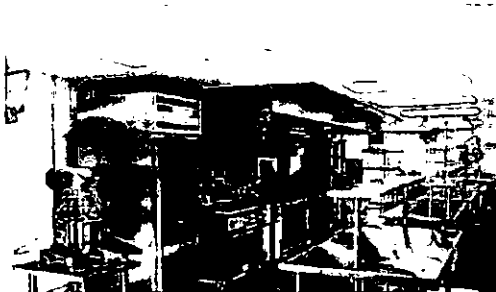
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# **THERMO-SAN™**

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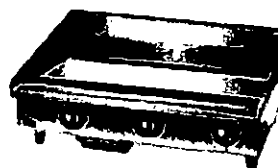
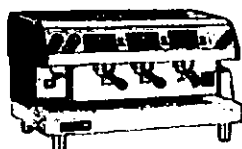
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**PET**



**HDPE**

[The following are company logos for use on PDI product labels. The purpose of the logo is for easy recognition of PDI products in the marketplace.]



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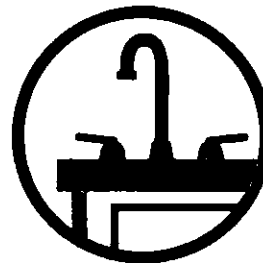
Dining Tables



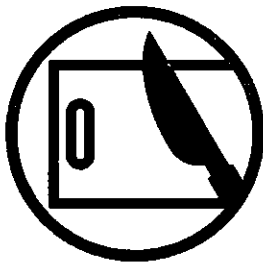
Food Preparation Tables



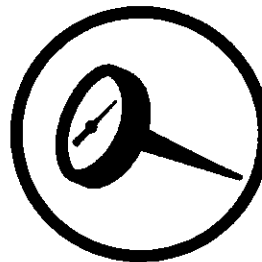
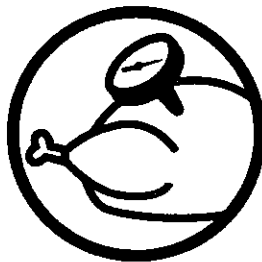
Counter Tops



Non-wood Cutting Boards



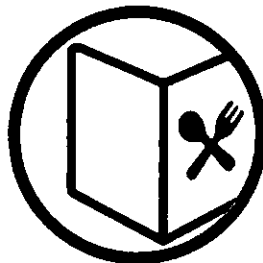
Probe Portion of Meat Thermometer



Thermometers,  
Steam Wands



Laminated Menus



Counters



Cafeteria Trays,  
Hospital Meal Trays  
Airline Tray Tables  
Pill Trays



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Bar Tops



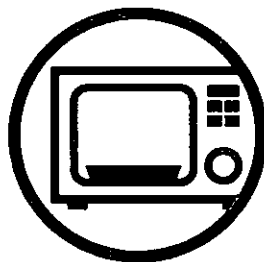
Waitress Stations



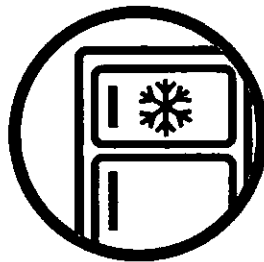
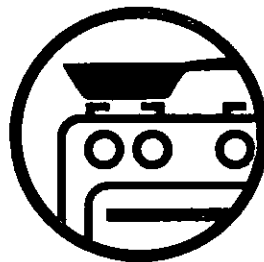
Food Carts



Microwaves, Ranges



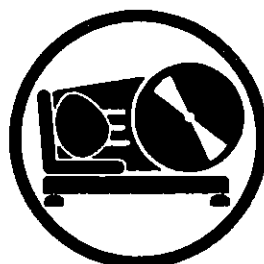
Refrigeration, Freezer Units



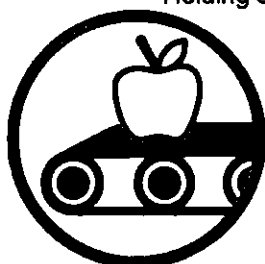
Self-Service Condiment Areas, Condiment Containers



Deli Slicer



Conveyor Belts,  
Conveyor Lines,  
Hopper Trays,  
Holding Containers



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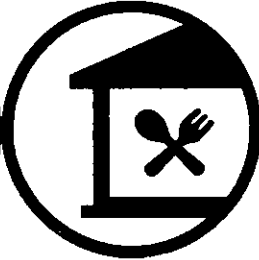
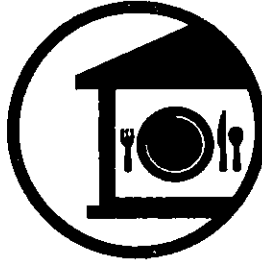
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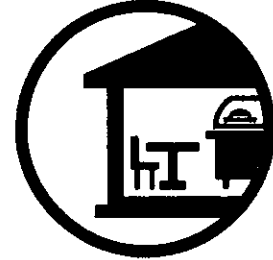
Small Wares  
(beverage dispensers,  
food mixers, scales)



Restaurants  
Foodservice



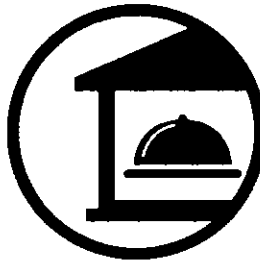
Dining Halls/Cafeterias



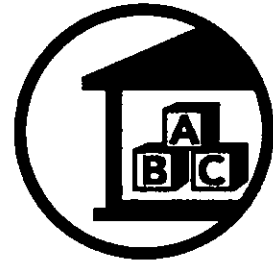
Airplanes/Airports



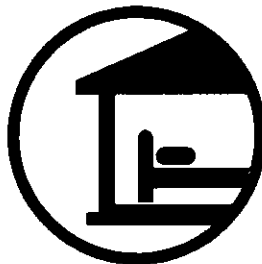
Caterers



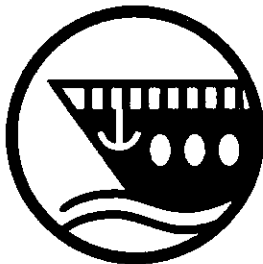
Daycare Settings



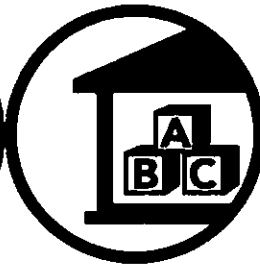
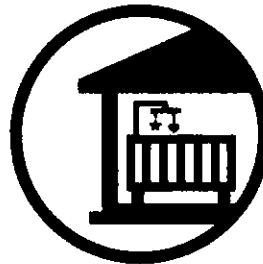
Hotels/Motels



Cruise Ships



Nurseries



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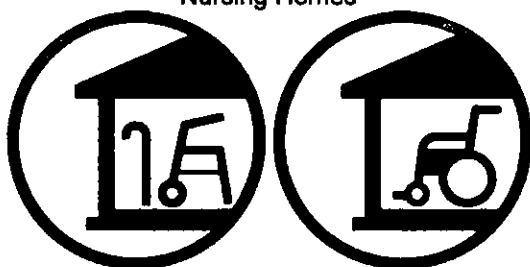
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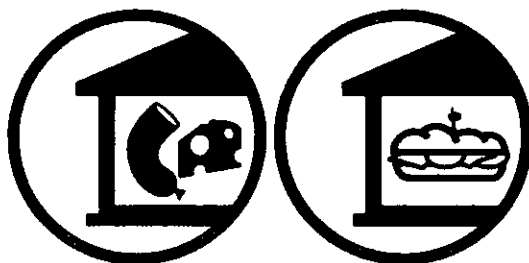
Nursing Homes



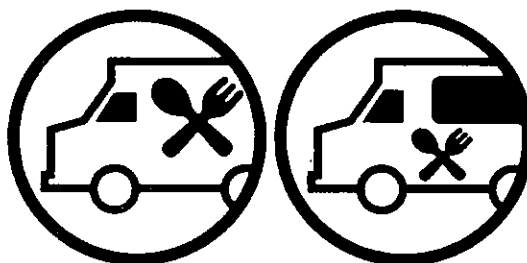
Schools



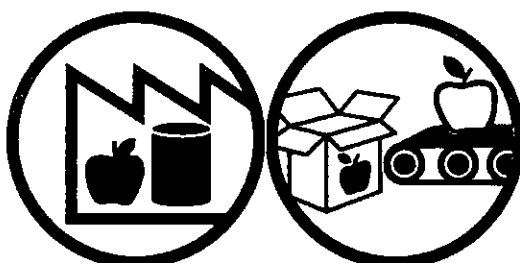
Delicatessens



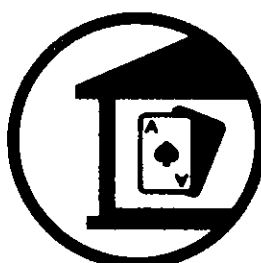
Food Trucks



Food Manufacturing Facilities



Casinos



Grocery



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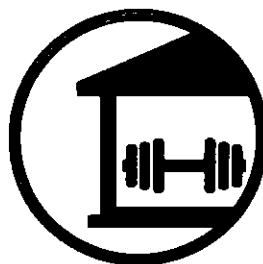
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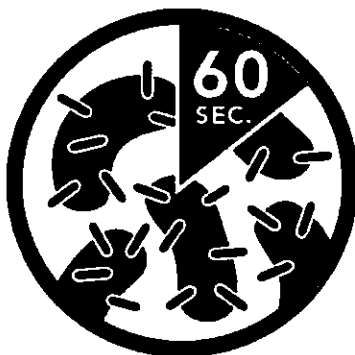
Convenience Stores



Fitness



Kills Listeria in 60 seconds



Kills Listeria in 1 minute



[Logo]



**THE INFORMATION IN BOX IS NOT PART OF THE LABELING**

[ ] - Statements in brackets are optional or instructional. Italicized words in brackets are not included

Sequence and placement of phrases is optional unless specified in 40 CFR 156.10.

Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR

The terms "Wipe(s)", "Towel(s)" and "Cloth(s)" can be used interchangeably throughout except for the product primary brand name which can be only changed by notification or amendment. Lists of uses and use sites can be used partially or in their entirety

F:\PD\19480-XX Backspin Wipe\Label\19480-RG label clean 032416.doc

Mar 24, 2016

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

**Office of Pesticide Programs**

**Antimicrobials Division (AD)**

March 7, 2016

DP BARCODE: 430057  
MRID: 49746400, 49746401, and 49746402  
SUBJECT: Backspin No-Rinse FCSS  
REG. NO.: 9480-RG  
DOCUMENT TYPE: Product Chemistry Review  
Manufacturing-use [ ] OR End-use Product [X]

**INGREDIENTS:**

<u>PC Code(s)</u>	<u>CAS Number</u>	<u>Active Ingredient(s)</u>
069105	68424-85-1	Alkyl* dimethyl benzyl ammonium chloride *(50%C <sub>14</sub> , 40%C <sub>12</sub> , 10%C <sub>16</sub> )
069149	7173-51-5	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride

TEST LAB: Case Laboratories Inc.  
SUBMITTER: Delta Analytical Corporation  
GUIDELINE: Group A and B Product Chemistry  
ORGANIZATION: AD\PSB\CTT  
REVIEWER: Lynette T. Umez-Eronini  
APPROVED BY: Karen P. Hicks  
APPROVED DATE: March 7, 2016  
COMMENT: This product is for use on non-food and food contact surfaces.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

**Office of Pesticide Programs**

**Antimicrobials Division (AD)**

March 7, 2016

**MEMORANDUM**

SUBJECT: Product Chemistry Review for EPA Reg. 9480-RG  
Product Name: Backspin No-Rinse FCSS

DP Barcode: 430057

DATE DUE: April 11, 2016

FROM: Lynette T. Umez-Eronini, Chemist  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

*Lynette T. Umez-Eronini*

THRU: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

*KRH*

TO: Eric Miederhoff PM #31/Karen Leavy  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Applicant: Professional Disposables International Inc.

CODE: A540 New Product; Non-Fast Track;

**PRODUCT FORMULATION FROM LABEL:**

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Didecyl dimethyl ammonium chloride	0.023
Alkyl (50%C <sub>14</sub> , 40%C <sub>12</sub> , 10%C <sub>16</sub> ) dimethyl benzyl ammonium chloride	0.015
<u>Other Ingredient(s):</u>	<u>99.962</u>
Total	100.000

## BACKGROUND:

On behalf of the registrant, Professional Disposables International, Inc., the consultant Delta Analytical Corporation has submitted an application to register a new non-integrated end-use product, Backspin No-Rinse FCSS. The product is a sanitizing wipe for use on hard nonporous food and nonfood contact surfaces. With the exception of the towelettes material, the product is identical to Backspray RTU (9480-RR).

The Product Chemistry Reviewer has received the following documents:

1. Cover letter, dated 10/20/2015.
2. Data Matrix - End Use, dated 10/9/2015.
3. Basic Confidential Statement of Formula (CSF), 10/09/2015.
4. Product Label, 10/7/2015.
5. Certification with Respect to Citation of Data, 10/9/2015.
6. EPA Form 8570-1, 10/20/2015.
7. Formulator's Exemption Statement, 10/9/2015.
- 8.

MRID	Citation
49746400	Same as above cover letter. Professional Disposables International, Inc. (2015) Submission of Product Chemistry and Efficacy Data in Support of the Application for Registration of Backspin No-Rinse FCSS. Transmittal of 7 Studies.
49746401	Griffin, C. (2015) Backspin No-Rinse FCSS: Product Identity, Manufacturing Process, and Enforcement Analytical Method. Project Number: 3710/59. Unpublished study prepared by Professional Disposables International, Inc. 24p.
49746402	Griffin, C. (2015) Backspin No-Rinse FCSS: Physical and Chemical Properties. Project Number: 3710/58. Unpublished study prepared by Professional Disposables International, Inc. 11p.

A revised data package was reviewed and included:

1. Email, 3/1/2016 from registrant to address the 830.1900 Submittal of Samples guideline.

## FINDINGS:

1. Basic CSF, dated 10/9/2015 and product label have the same nominal concentrations for the active ingredients.
2. All certified limits are within the EPA Standard Certified Limits.
3. All inerts are approved for food-use in antimicrobial formulations.
4. All ingredients in this formulation are approved for use in pesticide formulations.
5. Group A product chemistry data requirements applicable to end-use products have been met (see MRID 49746401 and Table A below).
6. Group B product chemistry data requirements applicable to end-use products have been met (see MRID 49746402 and Table B below).
7. A 14-day accelerated storage stability and corrosion characteristics study was done at  $54^{\circ}\text{C} \pm 2^{\circ}\text{C}$  (see MRID 49686302). Analysis of the total concentration of active ingredients in the product was done in duplicates at the initial and 14 day interval.

Table of Results of Storage Stability

Interval	Total Quaternary Amine, ppm		
	Replicate 1	Replicate 2	Average
Initial	384 ppm	386 ppm	385 ppm
After 14 days at $54^{\circ}\text{C} \pm 2^{\circ}\text{C}$	378 ppm	380 ppm	379 ppm

Storage Stability results showed the total concentration of active ingredients fall within EPA Standard Certified Limits. Corrosion Characteristics study showed no corrosion present on the commercial packaging material, HDPE.

8. The CSF reports a range for the pH and density. MRID 49746402 and Group B table (below) cite a single value for the pH and density. The pH and density on the CSF are consistent with that given on the said MRID and Group B table below.

## CONCLUSION:

The Basic CSF, 9/24/2015 is acceptable. Group A and B Product Chemistry data requirements have been met.

It may be noted that the policy on antimicrobial towelettes and wipes is under consideration by the Antimicrobial Division. Once the policy has been finalized, registrants will be informed if there are changes that need to be made regarding the registration process and if there are any additional data that must be submitted to the Division for review.

## I. CONFIDENTIAL STATEMENT OF FORMULA

• Non-integrated formulation system	Yes [X]	No [ ]
• Are all TGAIs used registered?	Yes [ ]	No [X]
• Integrated formulation system	Yes [ ]	No [X]
• If "ME-TOO," specify EPA Reg. No. of existing product:		

The product is cleared for food under 40 CFR §180.940 and §180.950.

Yes [X]      No [ ]

**Liquid**

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes ☒ No ☐

Yes ☒ No ☐

f. Active ingredient	<u>NC(%)</u>	<u>UCL(%)</u>	<u>LCL(%)</u>
1-Decanaminium, N-decyl-N,N-dimethyl-, chloride Alkyl (50%C <sub>14</sub> , 40%C <sub>12</sub> , 10%C <sub>16</sub> )	0.023	0.024	0.0223
dimethyl benzyl ammonium chloride	0.015	0.016	0.0142

- Do all impurities of toxicological significance have a UCL?  
Yes [ ]      No [ ]      Not applicable [X]
- Have all impurities of  $\geq 0.1\%$  in the product been identified?  
Yes [ ]      No [ ]      Not applicable [X]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☒ No ☐

b. The formula contains one of the following:

- |                                          |                              |                                        |
|------------------------------------------|------------------------------|----------------------------------------|
| • 10% or more of a petroleum distillate: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • 1.0% or more of methyl alcohol:        | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • sodium nitrite at any level:           | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • a toxic List 1 inert at any level:     | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • arsenic in any form:                   | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes ☐ No ☐ Not applicable ☒

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes ☒ No ☐ Not applicable ☐

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes ☒ No ☐

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes ☐ No ☐

**Table A:**  
**Product Chemistry (Series 830, Group A)**

<b>Data Requirements</b>	<b>Acceptance of Information</b>	<b>MRID No.</b>
830.1550 Product Identity <sup>1</sup>	A	49746401
830.1600 Description of Materials	A	49746401, 49686301
830.1620 Production Process <sup>2</sup>	NA	
830.1650 Formulation Process <sup>3</sup>	A	49746401
830.1670 Formation of Impurities <sup>4</sup>	NA	
830.1700 Preliminary Analysis <sup>5</sup>	NA	
830.1750 Certified Limits <sup>6</sup>	A	49746401
830.1800 Enforcement Analytical Method <sup>7</sup>	A	49746401, 49686301
830.1900 Submittal of Samples	A	Email, dated 3/1/2016

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

<sup>1</sup>See Confidential Appendix A for additional information.

<sup>2</sup>For MP/EP products produced by an integrated formulation system.

<sup>3</sup>For products from a TGA or MP.

<sup>4</sup>May be waived unless actual/possible impurities are of toxicological concern.

<sup>5</sup>Five batch analysis required for products produced by an integrated formulation system.

<sup>6</sup>If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

<sup>7</sup>Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

**Table B:**  
**Physical and Chemical Characteristics (Series 830, Group B)**

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA		
830.6303 Physical State	A	Cloudy Liquid	49746402
830.6304 Odor	NA		
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	Not applicable - product is ready to use and not mixed with chemicals.	49746402
830.6315 Flammability/Flame Extension	A	Flash point: 37°C	49746402
830.6316 Explodability	A	Not applicable - product is not potentially explosive.	49746402
830.6317 Storage Stability (14-Day Accelerated Study at 54°C ±2°C)	A	No physical changes were noted for the test substance.	49746402 (See 49686302)
830.6319 Miscibility <sup>1</sup>	A	Not applicable - product is no diluted with petroleum solvents.	49746402
830.6320 Corrosion Characteristics(14-Day Accelerated Study at 54°C ±2°C)	A	No corrosion present on the commercial packaging material, HDPE	49746402 (See 49686302)
830.6321 Dielectric Breakdown Voltage	A	Not applicable - product is not to be used around electric equipment.	49746402
830.7000 pH <sup>2</sup>	A	10.13 (1% solution at 25 °C)	49746402
830.7050 UV/Visible Absorption	NA		
830.7100 Viscosity (Average)	A	1.866 cSt at 22°C 1.095 cSt at 43.5°C	49746402
830.7200 Melting Point/Melting Range	NA		

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative Density/Bulk Density	A	0.9824	49746402
830.7370 Dissociation Constants in Water	NA		
830.7550/830.7560/830.7570 Partition Coefficient	NA		
830.7840/830.7860 Water Solubility	NA		
830.7950 Vapor Pressure	NA		

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

\* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

<sup>1</sup>If product is an emulsifiable liquid

<sup>2</sup>If product is dispersible with water



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460



OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Antimicrobial Division

March 1, 2016

DP BARCODE: 430055

MRID(s): 496863-03,-04,-05,-06,-07,-08

SUBJECT: Backspin No-Rinse FCSS

REG. NO. OR FILE SYMBOL: 9480-RG

DOCUMENT TYPE: Acute Toxicity Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number(s)	Active Ingredient(s):
069105	68424-85-1	Alkyl dimethyl benzyl ammonium chloride (50% C14, 40% C12, 10% C16)
069149	7173-51-5	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride (a.k.a. Didecyl dimethyl ammonium chloride)

TEST LAB: Tox Monitor Laboratories, Inc

SUBMITTER: Professional Disposables International, Inc

GUIDELINE(s): 870.1100, 870.1200, 870.1300, 870.2400, 870.2500, 870.2600.

COMMODITIES: N/A

REVIEWER: Boris S. Yurchak ORGANIZATION: AD/PSB/CTT

APPROVER: Karen P. Hicks APPROVED DATE: 3/3/2016

COMMENT: This product is for food and non-food use

B. Y.  
3/4/2016

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460



OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Antimicrobial Division

March 1, 2016

**MEMORANDUM**

**SUBJECT:** Acute Toxicity Review for EPA Reg. No. 9480-RG  
Product Name: Backspin No-Rinse FCSS  
DP Barcode: 430055

**TO:** Eric Miederhoff / Karen Leavy  
PM Team # 31

**FROM:** Boris S. Yurchak, Chemist  
Product Science Branch, CT Team  
Antimicrobials Division (7510P)

**THRU:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
Antimicrobials Division (7510P)

**APPLICANT:** Professional Disposables International, Inc  
**Action code:** (A540) New product; non-fast track  
**Due out date:** March 12, 2016

Two handwritten signatures in black ink. The top signature is "Eric Miederhoff" and the bottom signature is "Boris S. Yurchak".

**PRODUCT FORMULATION FROM LABEL:**

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Alkyl dimethyl benzyl ammonium chloride (50% C14, 40% C12, 10% C16)	0.015
Didecyl dimethyl ammonium chloride	0.023
<u>Other Ingredient(s)*</u>	<u>99.962</u>
TOTAL	100.000

## BACKGROUND:

The registrant is submitting 6 acute toxicity studies to support the registration of the subject product, Backspin No-Rinse FCSS, EPA Reg. No. **9480-RG**. MRID's are as follows: 496863-03 (81-1), 496863-04 (81-2), 496863-05 (81-3), 496863-06 (81-4), 496863-07 (81-5) and 496863-08 (81-6). The studies were conducted by Tox Monitor Laboratories, Inc. The test material used in the studies was Back Spray RTU (EPA Reg. No. 9480-RR) that is substantially similar to the subject product. The product is used to sanitize non-porous food contact and hard non-porous non-food contact surfaces.

### The data package included:

1. Cover letter from Registrant to EPA, dated 10/20/2015
2. Application for pesticide registration, Form 8570-1
3. Transmittal document, dated 10/20/2015
4. Basic Confidential Statements of Formula (CSF), dated 10/20/2015
5. Proposed label, punch dated 10/21/2015

## FINDINGS:

1. The acute toxicity studies cited 81-1 thru 81-6 were previously reviewed by AD/PSB for product EPA Reg. No. 9480-RR (DP429897, 01/08/2016) and found to be acceptable.
2. The acute toxicity profile for EPA Reg. No. **9480-RG** is currently:

GRN	Study	MRID	Toxicity Category	Status
81-1	Acute Oral Toxicity	49686303	IV	Cited
81-2	Acute Dermal Toxicity	49686304	IV	Cited
81-3	Acute Inhalation Toxicity	49686305	IV	Cited
81-4	Primary Eye Irritation	49686306	IV	Cited
81-5	Primary Dermal Irritation	49686307	IV	Cited
81-6	Dermal Sensitization	49686308	Non-sensitizer	Cited

## CONCLUSION:

The acute toxicity requirements have been satisfied for the subject product EPA Reg. No. 9480-RG.

### Product Labeling

Based on the above acute toxicity profile, no specific First Aid or human-hazard precautionary statements (or headings) are required except the front-panel statement "Keep Out of Reach of Children". (The Agency PM may, in accordance with 40 CFR §156.66, decide whether to waive this requirement, and whether to approve its placement on other than the front panel.)

The presence of the signal word is optional. (If one is used, it must be "CAUTION".)

11/12/15

Decision #: 510383

DP #: (430055)

PRIA

Parent DP #:

Submission #: 975899

E-Sub #:

**DATA PACKAGE BEAN SHEET**

Date: 09-Nov-2015

Page 1 of 1

**\*\*\* Registration Information \*\*\*****Registration: 9480-RG - BACKSPIN NO-RINSE FCSS**

Company: 9480 - PROFESSIONAL DISPOSABLES INTERNATIONAL, INC.

Risk Manager: RM 31 - Eric Miederhoff - (703) 347-8028 Room# PY1 S-8217

Risk Manager Reviewer: Karen Leavy KLEAVY

Sent Date: \_\_\_\_\_

PRIA Due Date: 11-Apr-2016

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (A540) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: 069105, Alkyl\* dimethyl benzyl ammonium chloride \*(50%C14, 40%C12, 10%C16)(.015%)

069149, 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride(.023%)

Karen  
as lead to  
do is before  
12/17/15

**\*\*\* Data Package Information \*\*\***Expedite: ☐ Yes ☒ No

Date Sent: 09-Nov-2015

Due Back: \_\_\_\_\_

DP Ingredient: 069105, Alkyl\* dimethyl benzyl ammonium chloride \*(50%C14, 40%C12, 10%C16)

069149, 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride

DP Title: \_\_\_\_\_

CST?

CSF Included: ☐ Yes ☒ NoLabel Included: ☒ Yes ☐ No

Parent DP #: \_\_\_\_\_

**Assigned To**

Date In

Date Out

Organization: AD / PSB

11/9

Last Possible Science Due Date: 12-Mar-2016

Team Name: CTT

11/10

Science Due Date: \_\_\_\_\_

Reviewer Name: Boris

11/12

Sub Data Package Due Date: \_\_\_\_\_

Contractor Name: Contractor

**\*\*\* Studies Sent for Review \*\*\***

No Studies

**\*\*\* Additional Data Package for this Decision \*\*\***

Can be printed on its own page

**\*\*\* Data Package Instructions \*\*\***

Technical Screen Review- Acute Tox. for this wipe product is being cited from the liquid product (EPA File Symbol # 9480-RR) which is currently being reviewed. The cited MRID Nos. are 49686303, 49686304, 49686305, 49686306, 49686307, 49686308. Technical Data Screen due date 12/28/15, PRIA Due Date 4/11/16, PRIA, Action Code A540, Split Review with efficacy and product chemistry. This data package includes a copy of the cover letter, proposed product labeling, and data matrices. The acute tox. DER should include both 9480-RR & 9480-RG.

Back Spicy 11/4


Boris, please send  
all data  
Please conduct  
T.S. Then give  
to Wallace  
for  
Contractor  
Review

Wallace yhs B needed back  
by Jan 2.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

DATA MATRIX - END USE

Date 10/09/15		EPA Reg. No./File Symbol 9480-		Page 1 of 1	
Applicant's/Registrant's Name & Address Professional Disposables International, Inc. (PDI) c/o Delta Analytical Corp., 12510 Prosperity Drive, Suite 160, Silver Spring, MD 20904		Product Backspin No-Rinse FCSS			
Ingredients: Didecyl dimethyl ammonium chloride, Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride					
Guideline Reference #	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>PRODUCT CHEMISTRY - PROD. IDENTITY, COMP. &amp; ANALYSIS</b>					
830.1550-830.1800	Product Identity, Manufacturing Process, and Analytical Method	To be assigned 49686301	PDI	OWN	
830.1900	Submittal of Samples	N/A	N/A	N/A	Available Up Request
830.6302-830.7300	Physical and Chemical Properties	To be assigned 49686302	PDI	OWN	
<b>TOXICITY</b>					
870.1100	Acute Oral Toxicity Study in Rats	49686303	PDI	OWN	
870.1200	Acute Dermal Toxicity Study in Rabbits	49686304	PDI	OWN	
870.1300	Acute Inhalation Toxicity Study in Rats	49686305	PDI	OWN	
870.2400	Acute Eye Irritation Study in Rabbits	49686306	PDI	OWN	
870.2500	Acute Dermal Irritation Study in Rabbits	49686307	PDI	OWN	
870.2600	Skin Sensitization Study in Guinea Pigs	49686308	PDI	OWN	
<b>PRODUCT PERFORMANCE</b>					
810.2300	PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: Staphylococcus aureus (ATCC 6538) Glass and Rough Plastic- 4ft. <sup>2</sup>	To be assigned	PDI	OWN	
	PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: Escherichia coli (ATCC 11229) Glass and Rough Plastic- 4ft. <sup>2</sup>	To be assigned	PDI	OWN	
	PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: Shigella boydii (ATCC 9207) Glass and Rough Plastic- 4ft. <sup>2</sup>	To be assigned	PDI	OWN	
	PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: Listeria monocytogenes (ATCC 19115) Glass and Rough Plastic- 4ft. <sup>2</sup>	To be assigned	PDI	OWN	
	Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modified for Pre-Saturated Towelette Product Application): Enterobacter aerogenes (ATCC 13048), Staphylococcus aureus (ATCC 6538)	To be assigned	PDI	OWN	
	Germicidal and Detergent Sanitizing Action of Disinfectants: Staphylococcus aureus (ATCC 6538)	49686309	PDI	OWN	
	Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces: Enterobacter aerogenes (ATCC 13048), Staphylococcus aureus (ATCC 6538)	49686310	PDI	OWN	
	Germicidal and Detergent Sanitizing Action of Disinfectants: Escherichia coli (ATCC 11229)	49686313	PDI	OWN	
	Germicidal and Detergent Sanitizing Action of Disinfectants: Listeria monocytogenes (ATCC 19117)	49686315	PDI	OWN	
	Germicidal and Detergent Sanitizing Action of Disinfectants: Shigella boydii (ATCC 9207)	49686318	PDI	OWN	
Signature 		Name and Title Cristina Griffin, Agent for PDI		Date 10/0915	

## Acute Toxicity Checklist for Technical Screens

Reg. No.: 9480-RG

Product name: Backspin No-Rinse FCSS

DP #: 430055

Technical Screen Due Date: 12/28/2015

1. Administrative:

☒ Label

☒ CSF

☒ Cover letter if any

☒ Transmittal Document

☒ All pertinent items that are listed in the Transmittal Document

☐ N\*\* The product name must be the same throughout the submission

2. Each data requirement must be addressed:

☒ 870.1100 - Acute Oral Toxicity

☒ 870.1200 - Acute Dermal Toxicity

☒ 870.1300 - Acute Inhalation Toxicity

☒ 870.2400 - Eye Irritation

☒ 870.2500 - Skin Irritation

☒ 870.2600 - Dermal Sensitization

3. For any data requirement:

☒ Study: Test substance must be clearly identified

☒ GLP: Statement of compliance or non-compliance – 40 CFR 160.12

☒ GLP Statement: Signed by director, submitter, and sponsor

☒ GLP: Statement of QA inspections – 40 CFR 160.35(b) (7)

☒ GLP: Study director signature and date – 40 CFR 160.185(b)

☐ N/A Waiver request: Rationale must be included

☒ Pass Screen ☐ Fail Screen

### Notes to PM

\*) CSF for the subject product was found in Data Jacket only.

\*\*) MRIDs are pertained to a product entitled Back Spray RTU (EPA Reg. No. 9480-RR) that formulation with the exception of the towelettes material is identical to the subject product (see cover letter).

Boris S. Yurchak

Chemist

12/07/2015



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL  
SAFETY AND POLLUTION  
PREVENTION

March 17, 2016

**MEMORANDUM**

**Subject:** Efficacy Review for Backspin No-Rinse FCSS; EPA File Symbol 9480-RG; DB  
Barcode: D430054.

**From:** Ibrahim Laniyan, Ph.D.  
Microbiologist  
Product Science Branch  
Antimicrobials Division (7510P)

**Thru:** Mark Perry, Team Leader  
Product Science Branch  
Antimicrobials Division (7510P)

**To:** Eric Miederhoff RM31 / Karen Leavy  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

**Applicant:** Professional Disposables International, Inc. (POI)  
Two Nice-Pak Park  
Orangeburg, NY 10962-1376

**Formulation from the Label:**

<u>Active Ingredient</u>	<u>% by wt.</u>
Didecyl dimethyl ammonium chloride .....	0.023 %
Alkyl (50% C <sub>14</sub> , 40% C <sub>12</sub> , 10% C <sub>16</sub> ) dimethyl benzyl ammonium chloride .....	0.015 %
<u>Other Ingredients:</u> .....	99.962 %
<u>Total</u> .....	100.000 %

## I. BACKGROUND

The product, Backspin No-Rinse FCSS (EPA File Symbol 9480-RG), is a new product. The applicant requested to register the product as a sanitizer for food and non-food contact hard, non-porous surfaces in household environments, industrial areas commercial, food processing. According to registrant, Backspin No-Rinse FCSS is a sanitizing wipe for hard nonporous food and nonfood contact surfaces. With the exception of the towelette material, the formulation is identical to the Backspray RTU (9480-RR), which is currently being reviewed at EPA. To support Backspin No-Rinse FCSS organism claims on the label, registrant is citing efficacy studies conducted on the Backspray RTU (9480-RR) for those specific claims. In addition, registrant is submitting four studies for efficacy testing conducted on the towelette. Also enclosed is one study for testing conducted on the towelette as a non-food contact sanitizer. Studies were conducted at MycoScience Labs, Inc., located at 25 Village Hill Rd, Willington, CT 06279; and Accuratus Lab Services, located at 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121.

This data package, identified as D430054, contained a letter from the applicant representative to EPA (dated October 20, 2015), EPA Form 8570-35 (Data Matrix), eleven studies under five MRID Nos. (497464-03 through 497464-07), Statements of No Data Confidentiality Claims for eleven studies, and the proposed label (dated October 7, 2015).

## II. USE DIRECTIONS

### TO SANITIZE [HARD NON POROUS FOOD-CONTACT SURFACES]:

**For Lightly Soiled Surfaces:** Use a [product name] wipe to clean the surface to be treated. Sanitize with additional [product name] wipes. Wipe enough for treated area to remain wet for one [1] minute [or 60 seconds]. Let air dry. No rinsing required.

**For heavily soiled surfaces:** Remove all food particles and soil from surfaces that are to be sanitized by thoroughly washing the surfaces with a detergent, followed by a potable water rinse before applying this [sanitizing wipe] [product name]. Wipe enough for treated area to remain wet for one [1] minute [or 60 seconds]. Let air dry. No rinsing required.

99.999% effective in one [1] minute [or 60 seconds] in the presence of 5% organic soil against *Escherichia coli* [(ATCC # 11229)], *Staphylococcus aureus* [(ATCC #6538)], *Shigella boydii* [(ATCC #9207)], and *Listeria monocytogenes* [(ATCC #19115)].

### [TO SANITIZE] [HARD NONPOROUS NONFOOD-CONTACT SURFACES]:

[Cleaning and] Sanitizing Procedure: Use a [product name] wipe to clean the surface to be treated. Sanitize surface with [product name] wipes. Wipe enough for treated area to remain wet for one [1] minute [or 60 seconds]. Let air dry. No rinsing required.

99.9% effective in 15 seconds against *Staphylococcus aureus* (ATCC #6538) and *Enterobacter aerogenes* (ATCC # 13048) [in the presence of organic soil (5% blood serum)].

## III. AGENCY STANDARDS FOR PROPOSED CLAIMS

**Antimicrobial Products for Use on Hard Surfaces Using Pre-saturated or Impregnated Towelettes:** Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in treating hard surfaces. The standard test methods available for hard surface disinfectants and



sanitizers, if followed exactly, would not closely simulate the way a towelette product is used. Agency guidelines recommend that a simulated-use test be conducted by modifying the standard test methods. Agency guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the surface of the carrier with the saturated towelette, and then subculturing the slides after a specified holding time. Performance standards of the standard test methods must be met. These Agency standards are presented in OCSPP 810. Guidelines, Pre-saturated or impregnated towelettes; and the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes.

#### IV. BRIEF DESCRIPTION OF THE DATA

**1. MRID 497464-03 "PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Staphylococcus aureus* (ATCC 6538) Glass and Rough Plastic- 4ft.<sup>2</sup>" for Backspin No-Rinse FCSS, by Richard Arsenault. Study conducted at MycoScience Labs, Inc. Study completion date – June 15, 16, and 17, 2015. Project Number 15-0079 NPNY, 15-0172 NPNY, and 15-0277 NPNY.**

These studies were conducted against *Staphylococcus aureus* (ATCC 6538). Three lot (Lot No. 7912-AE-937-004A, 7912-AE-937-004B, and 7912-AE-937-004C) of the product, Backspin No-Rinse FCSS, were tested according to MycoScience Labs protocols GLP-15-001 Rev.00, GLP-15-005 Rev.00, and GLP-15-010 Rev.00 (copies provided), against the target microorganisms for a contact time of 30 seconds at 20-23°C and 10 - 19% RH. Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. A 2' x 2' (4ft<sup>2</sup>) surface was comprised of eight 6" x 12" glass or rough plastic surface sections. Each 6" x 12" surface was inoculated with 0.125mL of the prepared culture suspension so that the total inoculum volume was 1.0 mL per 2' x 2' (4ft<sup>2</sup>) total surface area. The inoculum was spread uniformly over each surface section using a sterile spreading stick. The inoculated surfaces were dried for 30 minutes at room temperature and humidity in a biological safety cabinet. The 2' x 2' (4ft<sup>2</sup>) surfaces were inoculated and tested in triplicate for both smooth glass and rough plastic for each lot. One 8" x 10" wipe was used to wipe an entire 2' x 2' (4ft.<sup>2</sup>) inoculated surface. The wipe was folded in half two times prior to wiping the first 6" x 12" surface section. Each surface section was wiped in a consistent manner up and down the surface and working from left to right across the entire surface, then back from right to left. This was repeated one additional time so that the entire inoculated 6" x 12" surface had been wiped in this manner two times. The wipe was rotated and re-folded as necessary for each surface section wiped, so that the maximum of wipe surface was used over the course of wiping an entire 2' x 2' surface. After contact time, each surface was transferred to a sterile composite bag containing 3,000mL of AOAC neutralizing blank solution. The wipe was transferred into a sterile jar containing 200mL of AOAC neutralizing blank solution. The composite bag containing the surface carriers was sonicated for 5 minutes in an ultrasonic bath, followed by thorough agitation by hand. Surface and wipe suspensions were assayed for surviving numbers of microorganisms using membrane filtration technique. 3mL and 30mL of the sample surface extract, and 2mL and 20mL of the wipe extracts were filtered through individual sterile bacterial retentive filters followed by a 50mL rinse with AOAC neutralizing blank solution. The membrane filters were transferred to the surface of Tryptone Glucose Extract Agar plates (TGEA-N), and were incubated for a minimum of 48 hours at 35-37°C, and then were enumerated. Controls included those for parallel positive control count, inoculum count, neutralization confirmation, purity, sterility, and viability. The final surface inoculum after drying was  $>7.5 \times 10^7$  CFU/ dried 2' x 2' (4ft<sup>2</sup>) glass surface or rough plastic surface.

**2. MRID 497464-04 "PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Escherichia coli* (ATCC 11229) Glass and Rough Plastic- 4ft.<sup>2</sup>" for Backspin No-Rinse FCSS, by Richard Arsenault. Study conducted at MycoScience Labs, Inc. Study completion date – June 16, and 17, 2015. Project Number 15-0135 NPNY, 15-0320 NPNY, and 15-0659 NPNY.**

These studies were conducted against *Escherichia coli* (ATCC 11229). Three lots (Lot Nos. 7912-AE-937-004A, 7912-AE-937-004B, and 7912-AE-937-047A) of the product, Backspin No-Rinse FCSS, were tested according to MycoScience Labs protocols GLP-15-004 Rev. 00, GLP-15-008 Rev. 00, and GLP-15-014 Rev. 00 (copies provided), against the target microorganisms for a contact time of 30 seconds at 20-23°C and 16-33% RH. Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. A 2' x 2' (4ft<sup>2</sup>) surface was comprised of eight 6" x 12" glass or rough plastic surface sections. Each 6" x 12" surface was inoculated with 0.125mL of the prepared culture suspension so that the total inoculum volume was 1.0 mL per 2' x 2' (4ft<sup>2</sup>) total surface area. The inoculum was spread uniformly over each surface section using a sterile spreading stick. The inoculated surfaces were dried for 30 minutes at room temperature and humidity in a biological safety cabinet. The 2' x 2' (4ft<sup>2</sup>) surfaces were inoculated and tested in triplicate for both smooth glass and rough plastic for each lot. One 8" x 10" wipe was used to wipe an entire 2' x 2' (4ft<sup>2</sup>) inoculated surface. The wipe was folded in half two times prior to wiping the first 6" x 12" surface section. Each surface section was wiped in a consistent manner up and down the surface and working from left to right across the entire surface, then back from right to left. This was repeated one additional time so that the entire inoculated 6" x 12" surface had been wiped in this manner two times. The wipe was rotated and re-folded as necessary for each surface section wiped, so that the maximum of wipe surface was used over the course of wiping an entire 2' x 2' surface. After contact time, each surface was transferred to a sterile composite bag containing 3,000mL of AOAC neutralizing blank solution. The wipe was transferred into a sterile jar containing 200mL of AOAC neutralizing blank solution. The composite bag containing the surface carriers was sonicated for 5 minutes in an ultrasonic bath, followed by thorough agitation by hand. Surface and wipe suspensions were assayed for surviving numbers of microorganisms using membrane filtration technique. 3mL and 30mL of the sample surface extract, and 2mL and 20mL of the wipe extracts were filtered through individual sterile bacterial retentive filters followed by a 50mL rinse with AOAC neutralizing blank solution. The membrane filters were transferred to the surface of Tryptone Glucose Extract Agar plates (TGEA-N), and were incubated for a minimum of 48 hours at 35-37°C, and then were enumerated. Controls included those for parallel positive control count, inoculum count, neutralization confirmation, purity, sterility, and viability. The final surface inoculum after drying was  $>7.5 \times 10^7$  CFU/ dried 2' x 2' (4ft<sup>2</sup>) glass surface or rough plastic surface.

**3. MRID 497464-05 "PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Shigella boydii* (ATCC 9207) Glass and Rough Plastic- 4ft.<sup>2</sup>" for Backspin No-Rinse FCSS, by Richard Arsenault. Study conducted at MycoScience Labs, Inc. Study completion date – June 19, 2015. Project Number 15-0678 NPNY, and 15-0682 NPNY.**

These studies were conducted against *Shigella boydii* (ATCC 9207). Two lots (Lot Nos. 7912-AE-937-047B, and 7912-AE-937-047C) of the product, Backspin No-Rinse FCSS, were tested according to MycoScience Labs protocols GLP-15-015 Rev. 00, and GLP-15-016 Rev. 00 (copies provided), against the target microorganisms for a contact time of 30 seconds at 23-25°C and 30-44% RH. Fetal bovine serum was added to each inoculum to achieve a 5% organic soil

load. A 2' x 2' (4ft<sup>2</sup>) surface was comprised of eight 6" x 12" glass or rough plastic surface sections. Each 6" x 12" surface was inoculated with 0.125mL of the prepared culture suspension so that the total inoculum volume was 1.0 mL per 2' x 2' (4ft<sup>2</sup>) total surface area. The inoculum was spread uniformly over each surface section using a sterile spreading stick. The inoculated surfaces were dried for 25 minutes at room temperature and humidity in a biological safety cabinet. The 2' x 2' (4ft<sup>2</sup>) surfaces were inoculated and tested in triplicate for both smooth glass and rough plastic for each lot. One 8" x 10" wipe was used to wipe an entire 2' x 2' (4ft<sup>2</sup>) inoculated surface. The wipe was folded in half two times prior to wiping the first 6" x 12" surface section. Each surface section was wiped in a consistent manner up and down the surface and working from left to right across the entire surface, then back from right to left. This was repeated one additional time so that the entire inoculated 6" x 12" surface had been wiped in this manner two times. The wipe was rotated and re-folded as necessary for each surface section wiped, so that the maximum of wipe surface was used over the course of wiping an entire 2' x 2' surface. After contact time, each surface was transferred to a sterile composite bag containing 3,000mL of AOAC neutralizing blank solution. The wipe was transferred into a sterile jar containing 200mL of AOAC neutralizing blank solution. The composite bag containing the surface carriers was sonicated for 5 minutes in an ultrasonic bath, followed by thorough agitation by hand. Surface and wipe suspensions were assayed for surviving numbers of microorganisms using membrane filtration technique. 3mL and 30mL of the sample surface extract, and 2mL and 20mL of the wipe extracts were filtered through individual sterile bacterial retentive filters followed by a 50mL rinse with AOAC neutralizing blank solution. The membrane filters were transferred to the surface of Tryptone Glucose Extract Agar plates (TGEA-N), and were incubated for a minimum of 48 hours at 35-37°C, and then were enumerated. Controls included those for parallel positive control count, inoculum count, neutralization confirmation, purity, sterility, and viability. The final surface inoculum after drying was  $>7.5 \times 10^7$  CFU/ dried 2' x 2' (4ft<sup>2</sup>) glass surface or rough plastic surface.

**4. MRID 497464-06 "PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Listeria monocytogenes* (ATCC 19115) Glass and Rough Plastic- 4ft.<sup>2</sup>" for Backspin No-Rinse FCSS, by Richard Arsenault. Study conducted at MycoScience Labs, Inc. Study completion date – June 22, and 23, 2015. Project Number 15-0785 NPNY, and 15-0786 NPNY.**

These studies were conducted against *Listeria monocytogenes* (ATCC 19115). Two lots (Lot Nos. 7912-AE-937-060A, and 7912-AE-937-060B) of the product, Backspin No-Rinse FCSS, were tested according to MycoScience Labs protocols GLP-15-017 Rev. 00, and GLP-15-018 Rev. 00 (copies provided), against the target microorganisms for a contact time of 30 seconds at 22-25°C and 31-44% RH. Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. A 2' x 2' (4ft<sup>2</sup>) surface was comprised of eight 6" x 12" glass or rough plastic surface sections. Each 6" x 12" surface was inoculated with 0.125mL of the prepared culture suspension so that the total inoculum volume was 1.0 mL per 2' x 2' (4ft<sup>2</sup>) total surface area. The inoculum was spread uniformly over each surface section using a sterile spreading stick. The inoculated surfaces were dried for 25 minutes at room temperature and humidity in a biological safety cabinet. The 2' x 2' (4ft<sup>2</sup>) surfaces were inoculated and tested in triplicate for both smooth glass and rough plastic for each lot. One 8" x 10" wipe was used to wipe an entire 2' x 2' (4ft<sup>2</sup>) inoculated surface. The wipe was folded in half two times prior to wiping the first 6" x 12" surface section. Each surface section was wiped in a consistent manner up and down the surface and working from left to right across the entire surface, then back from right to left. This was repeated one additional time so that the entire inoculated 6" x 12" surface had been wiped in this manner two times. The wipe was rotated and re-folded as necessary for each surface section wiped, so that the maximum of wipe surface was used over the course of wiping an entire 2' x 2' surface.

After contact time, each surface was transferred to a sterile composite bag containing 3,000mL of AOAC neutralizing blank solution. The wipe was transferred into a sterile jar containing 200mL of AOAC neutralizing blank solution. The composite bag containing the surface carriers was sonicated for 5 minutes in an ultrasonic bath, followed by thorough agitation by hand. Surface and wipe suspensions were assayed for surviving numbers of microorganisms using pour plate technique. Appropriate aliquots, such as 3mL and 30mL of the sample surface extract, and 2mL and 20mL of the wipe extracts, were plated to tempered molten Brain Heart Infusion Agar (BHIA-N) containing stock AOAC neutralizer solution. 20mL and 30mL aliquots were plated by evenly splitting 10 mL aliquot portions and plating to large 150mm x 15mm plates. 2mL and 3mL aliquots were plated directly to standard 100mm x 15mm plates. The plates were mixed thoroughly and allowed to solidify, and incubated for 48 +/- 2 hours at 36 +/- 1 °C. After the incubation period, the plates were enumerated. Controls included those for parallel positive control count, inoculum count, neutralization confirmation, purity, sterility, and viability. The final surface inoculum after drying was  $>7.5 \times 10^7$  CFU/ dried 2' x 2' (4ft<sup>2</sup>) glass surface or rough plastic surface.

**5. MRID 497464-07 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Pre-Saturated Towelette Product Application)" Test Organism: *Staphylococcus aureus* (ATCC 6538) for Backspin No-Rinse FCSS, by Jamie Herzan. Study conducted at Accuratus Lab Services. Study completion date – June 17, 2015. Project Number A18356.**

This study was conducted against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 7912-AE-937-047A, 7912-AE-937-0478, and 7912-AE-937-047C) of the product, Backspin No-Rinse FCSS, were according to Accuratus Lab Services protocol NPP01042415.NFS (copy provided). Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. The product was received ready to use. Five sterile glass carriers per organism were inoculated with 0.02 ml of a 48-54 hour old suspension of the test organism. The carriers were dried at 35-37°C at 40% relative humidity for 20 minutes. One towelette was used to treat 5 carriers. Each carrier was wiped with a saturated pad back and forth for a total of 4 passes. The product delivered by this wiping was allowed to remain on the carrier surface for 15 seconds at 20 °C and 53% RH. After exposure, each carrier was transferred to 20 ml of neutralizer using identical staggered intervals. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 ml and 0.100 ml aliquots of the neutralized solution (10°) were plated onto the recovery agar plate medium. (Tryptic soy agar with 5% sheep's blood). The *S. aureus* plates were incubated at 35-37°C for 48±4 hours. The *E. aerogenes* plates were incubated for 48±4 hours at 25-32°C. Following incubation, the subcultures were visually enumerated. Controls included those for carrier quantitation, dry carrier count, inoculum count, neutralization confirmation, purity, sterility, and viability.

Note: Protocol amendments reported in the study were reviewed.

## V. RESULTS

MRID #	Microorganism	Lot	Surface	CFU Recovered	Control Count	% Reduction
	<i>Staphylococcus aureus</i>	7912-AE-937-004A	Rough Plastic	<193.67	$7.83 \times 10^7$	≥99.999%
			Smooth Glass	<476.67	$7.85 \times 10^7$	≥99.999%
			Rough Plastic	<143.33	$8.83 \times 10^7$	≥99.999%

497464-03	(ATCC # 6538)	7912-AE-937-004B	Smooth Glass	<116.67	$1.01 \times 10^8$	$\geq 99.999\%$
		7912-AE-937-004C	Rough Plastic	<176.67	$1.24 \times 10^8$	$\geq 99.999\%$
			Smooth Glass	$9.36 \times 10^2$	$2.58 \times 10^8$	$\geq 99.999\%$
497464-04	<i>Escherichia coli</i> (ATCC # 11229)	7912-AE-937-004A	Rough Plastic	<120	$8.10 \times 10^7$	$\geq 99.999\%$
			Smooth Glass	<110	$7.91 \times 10^7$	$\geq 99.999\%$
		7912-AE-937-004B	Rough Plastic	180	$1.04 \times 10^8$	$\geq 99.999\%$
			Smooth Glass	<110	$2.08 \times 10^8$	$\geq 99.999\%$
		7912-AE-937-047A	Rough Plastic	280	$1.37 \times 10^8$	$\geq 99.999\%$
			Smooth Glass	<110	$8.98 \times 10^7$	$\geq 99.999\%$
497464-05	<i>Shigella boydii</i> (ATCC 9207)	7912-AE-937-047B	Rough Plastic	<1243.33	$1.67 \times 10^8$	$\geq 99.999\%$
			Smooth Glass	<110	$2.24 \times 10^8$	$\geq 99.999\%$
		7912-AE-937-047C	Rough Plastic	<143.33	$1.84 \times 10^8$	$\geq 99.999\%$
			Smooth Glass	<110	$1.22 \times 10^8$	$\geq 99.999\%$
497464-06	<i>Listeria monocytogenes</i> (ATCC 19115)	7912-AE-937-060A	Rough Plastic	$1.36 \times 10^3$	$4.44 \times 10^8$	$\geq 99.999\%$
			Smooth Glass	896.67	$2.56 \times 10^8$	$\geq 99.999\%$
		7912-AE-937-060B	Rough Plastic	653.33	$1.85 \times 10^8$	$\geq 99.999\%$
			Smooth Glass	266.67	$8.26 \times 10^7$	$\geq 99.999\%$
497464-06	<i>Enterobacter aerogenes</i> (ATCC 13048)	7912-AE-937-047A	Glass carriers	<20	$2.95 \times 10^6$	>99.9%
		7912-AE-937-0478		<20		>99.9%
		7912-AE-937-047C		<20		>99.9%
	<i>Staphylococcus aureus</i> (ATCC 6538)	7912-AE-937-047A		<20	$75 \times 10^6$	>99.9%
		7912-AE-937-0478		<20		>99.9%
		7912-AE-937-047C		<20		>99.9%

## VI. RESULTS

1. The following efficacy data **support** the use of the product, Backspin No-Rinse FCSS (EPA File Symbol 9480-RG), as a food contact surface sanitizer against the following microorganisms for a contact time of 30 seconds at room temperature.

MRID # 497464-03	<i>Staphylococcus aureus</i> (ATCC 6538)
MRID # 497464-04	<i>Escherichia coli</i> (ATCC # 11229)
MRID # 497464-05	<i>Shigella boydii</i> (ATCC 9207)
MRID # 497464-06	<i>Listeria monocytogenes</i> (ATCC 19115)

2. The submitted (MRID # 497464-07) efficacy data **support** the use of the product, Backspin No-Rinse FCSS (EPA File Symbol 9480-RG), as a non-contact surface sanitizer against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538) for a contact time of 15 seconds at room temperature.

## VII. LABEL

1. The proposed label claims that the product, Backspin No-Rinse FCSS (EPA File Symbol 9480-RG), is a food contact sanitizer against the following for a contact time of 1 minute, at room temperature; **are supported** by the applicant's data.

*Staphylococcus aureus* (ATCC 6538)  
*Escherichia coli* (ATCC # 11229)  
*Shigella boydii* (ATCC 9207)  
*Listeria monocytogenes* (ATCC 19115)

2. The proposed label claims that the product, Backspin No-Rinse FCSS (EPA File Symbol 9480-RG), is a non-food contact sanitizer against the following for a contact time of 1 minute, at room temperature; **are supported** by the applicant's data.

3. The applicant must make the following changes to the proposed label, as appropriate:

- On page 6 of the proposed label, revise "Helps prevent cross-contamination by killing bacteria on the surface and on the wipe" to read "Helps prevent cross-contamination by killing bacteria on **treated** surface and on the wipe".
- On Page 7 of the proposed label, revise "Simply pull, wipe, and toss to help reduce the risk of cross-contamination" to read "Simply pull, wipe, and toss to help reduce the risk of cross-contamination **between treated surfaces**".
- On page 6 remove "infection prevention" and "foodborne illness protection"
- On page 9 change "...effective against all surface areas to which..." to read "...effective against all hard, non-porous surface areas to which..."

1/12/16

**Yurchak, Boris**

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**From:** Powell, Wallace  
**Sent:** Monday, January 11, 2016 7:57 PM  
**To:** Yurchak, Boris  
**Cc:** Hicks, Karen; Edwards, Latangila  
**Subject:** Contractor review for DP 430055  
**Attachments:** Action 9-59 Task Assignment Form.docx; 9-59 ~~9480-RG-D430055~~ Backspin No-Rinse FCSS-FINAL.docx  
  
**Importance:** High

Boris,

The contractor's review is attached.

Please rate the contractor's review:

3/Superior, 2/Adequate, 1/Deficient. Other remarks are optional but helpful.

FYI: ~~PSB due Mar 12~~, AD/PRIA due Apr 11.

Wallace

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**From:** Bob Ross [mailto:utross1@aol.com]  
**Sent:** Tuesday, January 05, 2016 7:13 PM  
**To:** Powell, Wallace <Powell.Wallace@epa.gov>  
**Cc:** 'Angie Edmonds' <edmondsam@aol.com>  
**Subject:** 9-59

Files are attached

**TASK ASSIGNMENT FORM (TAF)**  
Antimicrobials Division/OPP

<b>Contractor:</b> Summitec Corporation	<b>Contract No.:</b> EP-W-11-014	<b>WAM / PO:</b> Wallace Powell / LaTangila Edwards 703-308-6407 / 703-305-7170
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**A -- Completed by WAM/PO**

<b>Product Chemistry:</b> _____	<b>Acute Toxicity:</b> <u>X</u>	<b>Product Efficacy:</b> _____	<b>Efficacy Protocol:</b> _____
<b>Registration No.:</b> 9480-RG	<b>DP Barcode:</b> 430055	<b>E-Submission No.:</b> none Submission No.:	
<b>TYPE</b>	<b>Registration:</b> <u>X</u>	<b>Re-registration:</b> _____	<b>Registration review:</b> _____
<b>Action No.:</b> 9-59	<b>Due Date:</b> 1/6/2016	<b>AD Contact:</b> Wallace Powell	
		<b>AD Reviewer:</b> B. Yurchak	

**Instructions:**

The studies to be reviewed are listed in the table below.

The studies are in Documentum, locatable by *MRID*.

Locate 1 other file (which may contain CBI) by entering "Action 9-59" in the Document Title search field in Documentum.

MRID	Study	GDLN #	Gov't Estimated Hours	Actual Hours Spent
49686303	Acute oral toxicity	870.1100		
49686304	Acute dermal toxicity	870.1200		
49686305	Acute inhalation toxicity	870.1300		
49686306	Eye irritation	870.2400		
49686307	Dermal irritation	870.2500		
49686308	Dermal sensitization	870.2600		
		<b>Totals:</b>	6	19
			<b>Studies</b>	<b>Est. Hours</b>
				16

<b>Date Sent:</b> 12/21/2015	
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**B -- Completed by Contractor**

<b>Date Delivered:</b> 1/5/16	<b>Electronic:</b> <u>X</u>	<b>Fed Ex:</b> _____	<b>Courier:</b> _____
<b>Principal Reviewers:</b> Donna Fefee, Tim Borges			



Issues/Comments for EPA Reviewer's Attention:    None that would affect acceptability

\_\_\_ Additional Comments attached



 <b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460		<div style="display: inline-block; border: 1px solid black; padding: 2px; margin: 2px;"><input type="checkbox"/> Registration</div> <div style="display: inline-block; border: 1px solid black; padding: 2px; margin: 2px;"><input type="checkbox"/> Amendment</div> <div style="display: inline-block; border: 1px solid black; padding: 2px; margin: 2px;"><input checked="" type="checkbox"/> Other</div>	OPP Identifier Number
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number 9480-13		2. EPA Product Manager Eric Miederhoff	
4. Company/Product (Name) Professional Disposables International, Inc. (PDI)/Backspin FCSS		3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Professional Disposables International, Inc. (PDI) 100 Phillips Parkway Montvale, NJ 07645  <input checked="" type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
<b>Section - II</b>			
<input type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Other - Explain below.	
<b>Explanation:</b> Use additional page(s) if necessary. (For section I and Section II.) Notification per PR Notice 98-10 to add Alternate Brand Names and minor changes. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.			
<b>Section - III</b>			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	
<b>Section - IV</b>			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Jean Claude Marcelin		Title Manager, Regulatory Affairs EPA Services	
		Telephone No. (Include Area Code) 201-746-8922	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) 
2. Signature 		3. Title Manager, Regulatory Affairs EPA Services	
4. Typed Name Jean Claude Marcelin		5. Date May 25, 2016	



May 25, 2016

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive, Room S-4900  
Arlington VA 22202

Attn: Eric Miederhoff, PM 31

**Re: Notification under PR Notice 98-10 to add alternate brand names and minor changes**

**Product:** Backspin FCSS  
**EPA Reg. No:** 9480-13  
**Company:** Professional Disposables International, Inc.

Dear Mr. Miederhoff:

I am submitting this notification per PR Notice 98-10 to add new alternate brand names for Backspin FCSS, EPA Reg. No. 9480-13

The label changes are as follows:

- New alternate Brand Names highlighted in yellow
- Page 1, added [USA] after zip code
- Page 1, added [Made in [USA] [with domestic and imported materials] *[insert country]*
- Page 7, added Pre-Moistened [Wipe][s]
- Page 15, added Sanitize and Sani® Professional teardrop logos

**Enclosures**

The following documents are enclosed in support of this application:

- EPA form 8570-1
- 1 copy of the revised label with changes highlighted in yellow

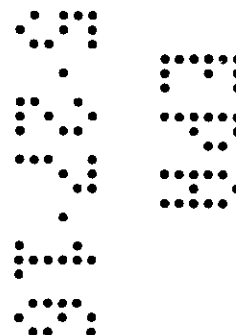
If you have any questions, please contact me at [jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com) or (201) 746-8922

Sincerely,



Jean Claude Marcelin

MANAGER, REGULATORY AFFAIRS EPA SERVICES  
NICE-PAK PRODUCTS, INC  
PROFESSIONAL DISPOSABLES INTERNATIONAL (PDI) INC.  
100 PHILIPS PARKWAY  
MONTVALE, NJ 07645  
P 201-746-8922  
[jmarcelin@pdipdi.com](mailto:jmarcelin@pdipdi.com)  
[pdipdi.com](http://pdipdi.com)



[Front Panel]

## BACKSPIN NO-RINSE FCSS

Alternate brand names: Sani Professional® No-Rinse Sanitizing Multi-Surface Wipe[s]  
[Grime Boss] Hard Surface Sanitizing Wipe[s]  
[Grime Boss] Surface Sanitizing Wipe[s]  
[Grime Boss] Surface Sanitizer  
[Grime Boss] Surface Sanitizing  
[Grime Boss] Sanitizing Wipe[s]  
[Grime Boss] No Rinse Sanitizing Wipe[s]  
[Grime Boss] Food Surface Sanitizing Wipe[s]  
[Grime Boss] Restaurant Sanitizing Wipe[s]

### ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chloride.....	0.023%
Alkyl (50% C <sub>14</sub> , 40% C <sub>12</sub> , 10% C <sub>16</sub> ) dimethyl benzyl ammonium chloride.....	0.015%
OTHER INGREDIENTS.....	99.962%
TOTAL.....	100.000%

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS [and/or Net Wt.] \_\_\_\_\_ oz (g) [or lbs. (kg)]  
[Insert number] Cloths [size of each cloth]

[Any Panel]

EPA Reg. No.: 9480-13

EPA Est. No.: 9480-NY-1 or [EPA Est. No. A=9480-NY-1, C=72956-AR-1 [or others]

Alpha character will precede batch code on product

[Manufactured by [or for]]:

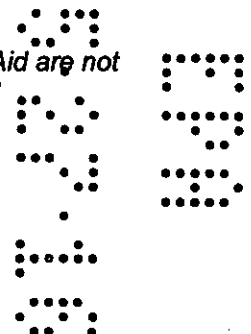
Professional Disposables International, Inc.

Two Nice-Pak Park, Orangeburg, NY 10962-1376 [USA]

[For information call: [phone number to be inserted]]

[Made in [USA] [with domestic and imported materials] [insert country]

[Note to Reviewer: According to EPA's Label Review Manual, Precautionary Statements and First Aid are not required for the registrant to include when the product is classified as Category IV for acute toxicity]



### THE INFORMATION IN BOX IS NOT PART OF THE LABELING

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Sequence and placement of phrases is optional unless specified in 40 CFR 158.10.

Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR

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notification or amendment. Lists of uses and use sites can be used partially or in their entirety

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## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

### TO SANITIZE [HARD NON POROUS FOOD-CONTACT SURFACES]:

**For Lightly Soiled Surfaces:** Use a [product name] wipe to clean the surface to be treated. Sanitize with additional [product name] wipes. Wipe enough for treated area to remain wet for one [1] minute [or 60 seconds]. Let air dry. No rinsing required.

**For heavily soiled surfaces:** Remove all food particles and soil from surfaces that are to be sanitized by thoroughly washing the surfaces with a detergent, followed by a potable water rinse before applying this [sanitizing wipe] [product name]. Wipe enough for treated area to remain wet for one [1] minute [or 60 seconds]. Let air dry. No rinsing required.

99.999% effective in one [1] minute [or 60 seconds] in the presence of 5% organic soil against *Escherichia coli* [(ATCC # 11229)], *Staphylococcus aureus* [(ATCC #6538)], *Shigella boydii* [(ATCC #9207)], and *Listeria monocytogenes* [(ATCC #19115)].

Items may include: [Use one or more of the following:]

[Airline tray tables]	[Fridges]	[Range tops and hoods]
[Appliances]	[High chair trays]	[Reach-in refrigeration and freezer units]
[Backsplashes]	[Hospital meal trays]	[Restaurant tables]
[Bar tops]	[Laminated menus]	[Scales]
[Cafeteria trays]	[Lunch boxes]	[Self-service condiment areas]
[Checkout lanes]	[Microwaves]	[Self-service serviceware areas]
[Condiment containers]	[Mixers]	[Slicers]
[Conveyer belts]	[Nonwood cutting boards]	[Tables]
[Counter tops]	[Nozzles]	[Take out counters]
[Cutting boards]	[Pill counters]	[Waitress stations]
[Dining tables]	[Pill trays]	[Walk-in refrigeration and freezer units]
[Dish racks]	[Probe portion of meat thermometers]	[Work tables]
[Food trays]	[Probe portion of food thermometers]	
[Food carts]	[Ranges]	
[Food preparation tables]		
[Food [manufacturing] [processing] [equipment][parts]]		

[The following uses must be preceded by the words: "outside surface[s] of]" or "[exterior surface[s] of]":]

[Beverage dispensers]	[Griddles]	[Steam tables]
[Broilers]	[Grills]	
[Chargrills]	[Ice machines]	[Toasters]
[Cooking surfaces]	[Pulpers]	
[Food mixers]	[Ovens]	

[Add the following after the list of surfaces:] and other similar hard, nonporous food contact surfaces.

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**[TO SANITIZE] [HARD NONPOROUS NONFOOD-CONTACT SURFACES]:**

[Cleaning and] Sanitizing Procedure: Use a [product name] wipe to clean the surface to be treated. Sanitize surface with [product name] wipes. Wipe enough for treated area to remain wet for 15 seconds. Let air dry. No rinsing required.

Use one or more of the following:

[bath tubs,]	[employee areas],	[restaurant chairs]	[telephones,]
[booster seats,]	[garbage cans,]	[shopping carts]	[tiled walls,]
[cash registers,]	[hampers,]	[and/or] [baskets,]	[toilet seats, [and/or]
[chairs,]	[hotel room surfaces]	[showers,]	[rims,]
[cribs,]	[and/or] [counters]	[sinks,]	[towel dispensers,]
[diaper pails]	[infant-changing	[stall doors,]	[vanities,]
[display cabinets,]	tables,]	[store] check-out	[trashcans]
[doorknobs,]	[infant high chairs,]	areas,	
[drain boards,]	[faucets,]	[strollers]	
	[floors,]		

99.9% effective in 15 seconds against *Staphylococcus aureus* (ATCC #6538) and *Enterobacter aerogenes* (ATCC # 13048) [in the presence of organic soil (5% blood serum)].

**[CLEANING AND DEODORIZING**

Wipe surface with towelette until clean. Let air dry.]

**Dispensing:** [Choose the dispensing directions from below that correspond to the product package.]

[On canister]

Remove lid and discard inner seal. Find center wipe and pull through lid. For optimal use, pull wipes at an angle. When not in use keep lid closed to prevent moisture loss.

[On Flexible Pack or Mobile Pack or Belt Pack]

Peel back label. Pull out wipes as needed. When not in use keep lid closed to prevent moisture loss.

[On Packet]

Tear open packet.

[Pail]

Remove lid and tear open refill package.

[Refill Package]

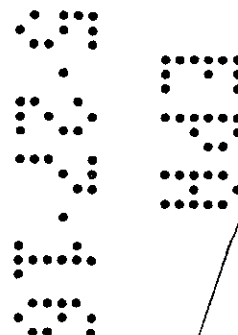
This refill package is made for use only in a [product name] container; do not use this product in a container for another product. Remove [entire] lid from container. Tear open refill [package] at [notch] [mark] [arrow]. Place [entire] refill package of wipes in empty container. Follow information on container to dispense wipes.

**PRECAUTIONARY STATEMENTS**

Hazards to Humans and Domestic Animals

**Physical or chemical hazard**

Combustible. Do not use or store near heat or open flame.

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## STORAGE AND DISPOSAL

**Storage:** Do not store near heat or open flame. Use product only from original container.

*[For canisters:]*

**Wipe Disposal:** Do not reuse wipe, offer for recycling. If recycling is not available, put in trash collection.

**Canister Disposal:** Do not reuse this container. Rinse and recycle. If recycling is not available, put in trash.

*[For flexible packs, mobile packs, belt packs or single packets:]*

**Wipe Disposal:** Do not reuse wipe, offer for recycling. If recycling is not available, put in trash collection.

**Flexpack Disposal:** Put empty package in trash collection.

*[For pail:]*

**Wipe Disposal:** Do not reuse wipe, offer for recycling. If recycling is not available, put in trash collection.

**Packaging Disposal:** Put empty package in trash collection.

**Pail Disposal:** Do not reuse this container. Rinse and recycle. If recycling is not available, put in trash.

*[Use at least one of the use sites indicated in the paragraph below or in the "For Use In" section below:]*

### [AREAS OF USE IN FOOD SERVICE AND FOOD PREPARATION:]

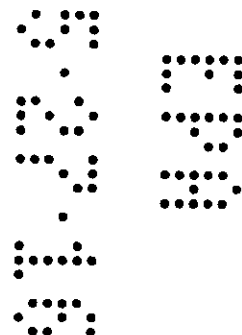
This product is recommended for use in retail food establishments [including:] [restaurants,] [hotels,] [kitchens,] [airplanes,] [food service in healthcare settings,] [delicatessens,] [supermarkets,] [temporary food establishments], [food processing plants,] and other food service and food preparation settings where the [control of the hazards] [prevention] of cross-contamination between treated surfaces is of primary importance.

### [FOR USE IN:]

[Airplanes]  
[Athletic facilities]  
[Banquet halls]  
[Beverage Processing Facilities]  
[Cafeterias]  
[Cars]  
[Caterers]  
[Catering facilities]  
[Correctional facilities]  
[Cruise Ships]  
[Day Care Settings]  
[Delicatessens]  
[Dining halls]  
[Drug Stores]  
[Food Manufacturing Facilities]  
[Food Packaging Facilities]

[Food Processing Facilities]  
[Food Service Facilities]  
[Food Trucks]  
[Funeral homes]  
[Gyms]  
[Grocery]  
[Healthcare Food Service]  
[Health clubs]  
[Homes residences]  
[Hotels]  
[Households]  
[Household kitchens and/or  
bathrooms]  
[In-Store Demos]  
[Kitchens]  
[Mobil Food Establishments]

[Mortuaries]  
[Motels]  
[Nurseries]  
[Nursing Homes]  
[Nutraceutical Production Facilities]  
[Pharmaceutical Production  
Facilities]  
[Pharmacy]  
[Poultry/Meat/Seafood Packing  
Facilities]  
[Restaurants]  
[Schools]  
[Shopping centers]  
[Temporary Food Establishments]  
[Transportation Centers]



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**[For use on the following[:] [types of surfaces:]]**

[Aluminum]  
[Chrome]  
[Corian®]  
[Finished Wood]  
[Finished Polyurethane]  
[Formica®]  
[Glazed Porcelain (Surfaces)]  
[Glazed Porcelain (Enamel)(Kitchen)(Tile)]  
[Laminated Surfaces (Laminate)]  
[Laminated Wood]  
[Metal]  
[Polystyrene]  
[Quartz]  
[Sealed Cement]  
[Sealed Granite]  
[Sealed Synthetic Marble]  
[Steel Surfaces]  
[Sealed Stone Surfaces]  
[Stainless Steel]

**Optional Label Claims**

*[All below are optional/ label (placement optional) literature and promotional statements]*

\*99.999% effective in 60 seconds against *Staphylococcus aureus* [(ATCC #6538)], *Escherichia coli* [(ATCC #11229)], *Shigella boydii* [(ATCC# 9207)], and *Listeria monocytogenes* [(ATCC# 19115)] on hard, nonporous food contact surfaces.

X ct. X *[to be replaced with unit packet count]*

Aids in the reduction of cross-contamination between treated surfaces. \*\*

All applicable health inspection agency code requirements must be followed for cleaning, rinsing and sanitizing.

Always follow directions for use on this [or the] label.

A convenient way to clean and sanitize

An efficient way to clean and sanitize

Antibacterial

Antimicrobial

Antimicrobial wipes

Bleach-free *[this is included as useful info for users needing a bleach-free product]*

By Grime Boss®

Cleans, deodorizes and kills common foodservice[foodborne] bacteria

Cleans, deodorizes and kills common household bacteria

Commercial use

Convenient wipes

Convenient way to sanitize. One wipe at a time.

*[for use on canisters, not packets]* Cost Savings: Our *[product name]* wipe is [X] times larger and [X]% less expensive than [PDI's or our [previous]] individually packed wipes. The easy grip canister contains [X] more wipes and creates less waste than individual packets. Now you can do more with less waste!

Designed and formulated for use on large hard nonporous surface areas *[list surfaces from approved list]*

Designed to be effective on large hard nonporous surfaces [including]: *[list surfaces from approved list]*

Designed to clean, then sanitize lightly soiled, hard, nonporous food contact surfaces [where the control of cross-contamination between treated surfaces is of primary importance]

Do not use on natural marble, windows, unpainted wood, brass, clear plastic or colored grout.

Each [or Every] wipe releases the right amount of sanitizer

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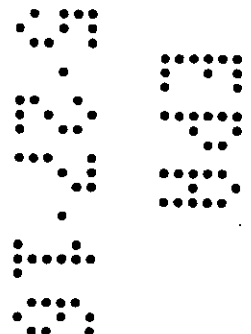
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Easy sanitizing on the go  
 Easy sanitizing for hard nonporous surfaces around the house [office] [bathroom] [kitchen]  
 Easy to use  
 Effective in sanitizing your hard nonporous surfaces [kitchen] [bathroom] surfaces  
 Eliminates odors  
 Every day use  
 Extra large wipes  
 Fast drying formulation  
 Fits with Swiffer sweepers  
 Food Code Compliant [*referencing 2013 Food Code*]  
 Food contact surface\*\* sanitizing wipe  
 Food processing [commercial] [industrial] use  
 For hard nonporous household surfaces  
 For your [heavy] [or light] duty jobs  
 For cleaning on the go  
 For use in food processing facilities where dry cleaning is [critical] [required] [for] [to] your operation] [*dry cleaning is a method of cleaning where it is necessary to keep water content at a minimum*]  
 For use in retail and institutional food establishments, food processing plants and other health department regulated food facilities. \*\*  
 For use on hard nonporous surfaces in [professional][commercial] kitchens  
 Incorporate as part of your [pathogen reduction] [or food safety] program  
 Ideal for Daily Use  
 Ideal for water-sensitive equipment  
 Industrial use [*only for use in products labeled for commercial uses*]  
 Helps prevent cross-contamination [by killing bacteria on the treated surface and on the wipe. \*\*]  
 [Its] [Product name's] quat-based formula is [EPA] registered  
 Kills 99.9% of *Staphylococcus aureus* [(ATCC #6538)] and *Enterobacter aerogenes* [(ATCC # 13048)] in 15 seconds [on hard, nonporous non food contact surfaces]  
 Kills 99.999% of *Staphylococcus aureus* [(ATCC #6538)], *Escherichia coli* [(ATCC #11229)], *Shigella boydii* [(ATCC# 9207)], and *Listeria monocytogenes* [(ATCC# 19115)] in 60 seconds on [cleaned] [and rinsed] hard, nonporous food contact surfaces  
 Kills 99.999% of *Listeria monocytogenes* [(ATCC# 19115)] on hard, nonporous food contact surfaces  
 Kills 99.999% of common foodborne pathogens  
 Kills bacteria on the wipe and on the surface  
 Kills [99.9% of] common household bacteria  
 Kills common household bacteria including: [*Staphylococcus aureus*] [Staph], [*Escherichia coli*] [E. coli], [*Shigella boydii*] [Shigella], and *Listeria monocytogenes* [Listeria]  
 Kills common foodborne pathogens including: [*Staphylococcus aureus*] [Staph], [*Escherichia coli*] [E. coli], [*Shigella boydii*] [Shigella], and *Listeria monocytogenes* [Listeria]  
 Kitchen surface wipes  
 Large enough to work with sweepers  
 Large enough to work with Grime Boss® Sweepers  
 Leaves no harsh chemical residue  
 Less waste than individually wrapped wipes  
 [Moisture] [Hydro-] lock lid  
 [Made in USA] [of Domestic and [Foreign][Imported] Materials] [Made in [*insert country*]]



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[Neutralizes] [Eliminates] odors No  
animal ingredients  
No mixing or measuring required  
[No mixing, no measuring, no problem]  
Noncorrosive formulation  
No-Rinse Sanitizer

Only for commercial uses  
Pre-Moistened [Wipe][s]

Premeasured, premoistened sanitizing wipes for use on hard nonporous surfaces.

[Product name] are a convenient method for sanitizing thermometers and other small wares

[Product name] can be part of your facilities' [Hazard Analysis Critical Control Point] [HACCP] plan.

[Product name], food contact sanitizing wipe formulated and designed to clean and sanitize [insert food  
contact surfaces].

Proven effective against foodborne pathogens listed below\*

\*99.999% effective in 60 seconds against *Staphylococcus aureus* [(ATCC  
#6538)], *Escherichia coli* [(ATCC #11229)], *Shigella boydii* [(ATCC# 9207)], and *Listeria monocytogenes*  
[(ATCC# 19115)] on hard, nonporous food contact surfaces.

Quick and easy sanitizing of [add use surfaces from this label]

Ready to use

Recommended for use on hard, nonporous nonfood contact surfaces as a sanitizer

Sanitizes food prep surfaces

Sanitizes [baby][children's] [booster chairs] [high chair trays] [strollers]

Sanitizes hard nonporous surfaces

Sanitizes interiors of [microwave ovens], [refrigerators], [stoves], [freezers], [food trays], [lunch boxes],  
[dishwashers], [dish racks], [sinks]

Sanitizing Wipe

Saves time

Say good-bye to dirty rags and buckets

Simply pull, wipe, and toss [to help reduce the risk of cross-contamination between treated surfaces] [!]

Streak-free cleaning

Strong wipe for tough jobs

Test in an inconspicuous area prior to use

The [Product name] formula is noncorrosive. [Compatible with] [or May be used on] [or Will not damage]:  
[Stainless steel] [and/or] [Small] [commercial kitchen wares]

The [X wipe size] of [product name] is large enough to use effectively on a variety of small wares and  
equipment of busy commercial kitchens. The [new] easy grip canister contains [count] wipes and  
creates less waste than individual packets. [product name]: Now you can do more with less waste!

The bacteria are killed in 60 seconds by contact with the liquid in the wipe. The product is effective when  
the surface is completely contacted with the wipe.

The fast, easy and effective way to sanitize hard, nonporous [food contact] [and] [nonfood contact]  
surfaces

The wet wipe for dry cleaning [dry cleaning is a method of cleaning where it is necessary to keep water  
content at a minimum]

The wipe is effective against all hard, nonporous surface areas to which all liquid has been imparted for the  
required contact time

[Trial] [Value] size

Use [as a part of] [in support of] your [FSMA-driven/compliant] HACCP plan

Use in conjunction with Sani Professional QuatCheck Kit to verify active level for your Health [Inspection  
authority] [Inspector]

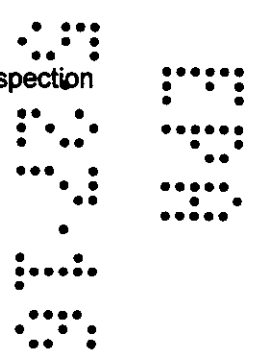
Use on hard nonporous surfaces wherever [sanitizing] is important

Use to sanitize hard nonporous surfaces during in-store food [demos] [or demonstrations]

Use to sanitize the probe portion of [food] [and] meat thermometers.

Use with [patent pending] [proprietary] [Triple Take Dispenser] [Belt Packs] [Wall Brackets]

User friendly



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notification or amendment. Lists of uses and use sites can be used partially or in their entirety

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Uses X% less plastic than similar count canisters

Versatile: The [wipe size] [Product name] size is ideal for use on thermometers, meat probes, steam wands, and small ware equipment.

Where compliance and guest experience meet

---

**6-Month Advertising Claims [product in marketplace 6 months]**

[Note: The following claims will be used as this product replaces a current PDI EPA registered product:]

[Use in place of] [replaces]: [previous product names]

Formerly marketed as [previous product names]

Our fastest drying formulation yet

New! Kills Listeria\* 99.999% of *Listeria monocytogenes* in 60 seconds.

Now! Kills 99.999% of *Listeria monocytogenes* [on hard, nonporous food contact surfaces]

Table Turners has a new look

Thermosan has a new look

Sani-Wipe has a new look

[\*\* hard nonporous surfaces only]

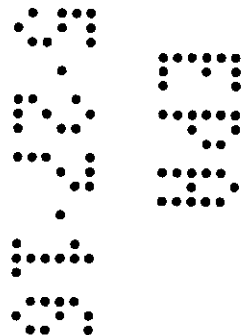
[Graphics depicting use sites listed on this label can appear on product label and labeling.]

[The following graphics and statements are optional.

They may be placed anywhere on label/container.]

**NOT FOR USE ON SKIN**

**FOR USE ON HARD NONPOROUS SURFACES ONLY**



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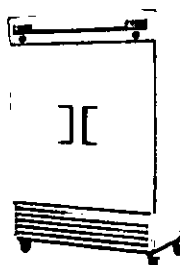
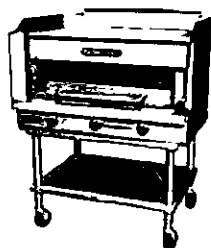
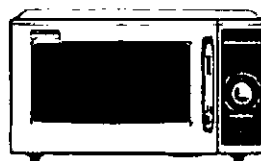
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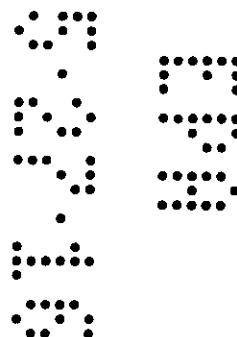
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*[The following graphics and statements are optional. They may be placed anywhere on label/container.]*



**THERMO-SAN™**



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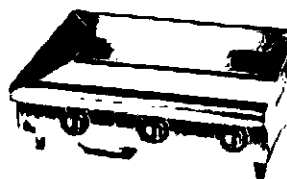
Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR

The terms "Wipe(s)", "Towel(s)" and "Cloth(s)" can be used interchangeably throughout except for the product primary brand name which can be only changed by notification or amendment. Lists of uses and use sites can be used partially or in their entirety

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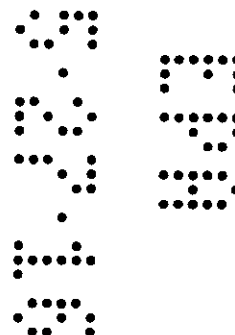


**PET**



**HDPE**

[The following are company logos for use on PDI product labels. The purpose of the logo is for easy recognition of PDI products in the marketplace.]



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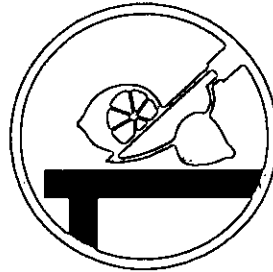
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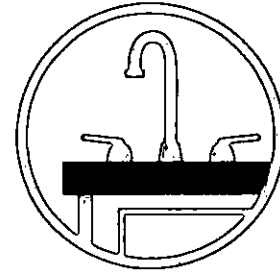
Dining Tables



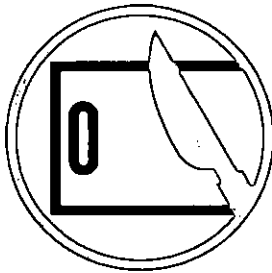
Food Preparation Tables



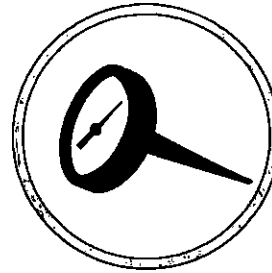
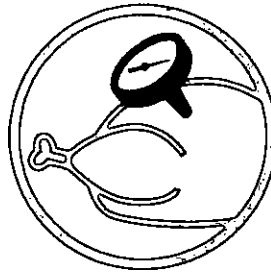
Counter Tops



Non-wood Cutting Boards



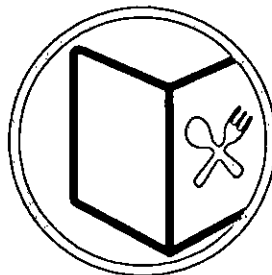
Probe Portion of Meat Thermometer



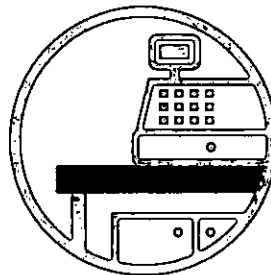
Thermometers,  
Steam Wands



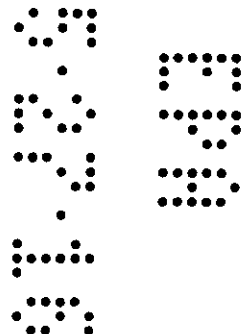
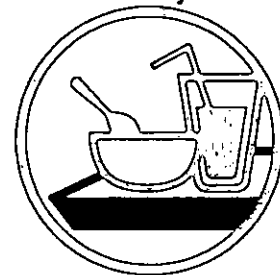
Laminated Menus



Counters



Cafeteria Trays,  
Hospital Meal Trays  
Airline Tray Tables  
Pill Trays



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Bar Tops



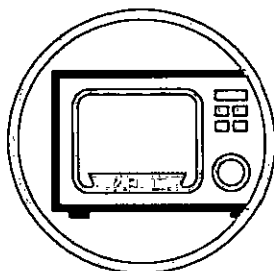
Waitress Stations



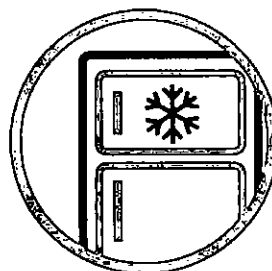
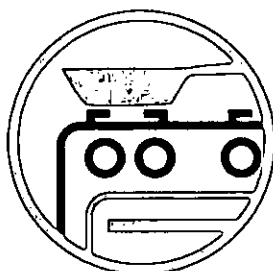
Food Carts



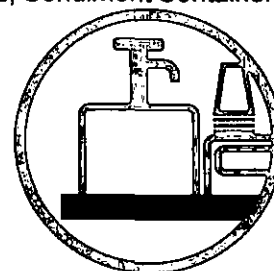
Microwaves, Ranges



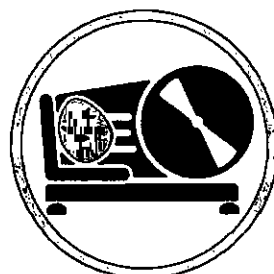
Refrigeration, Freezer Units



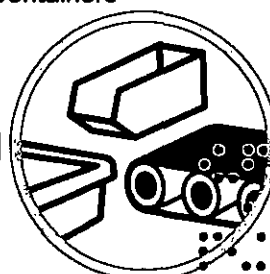
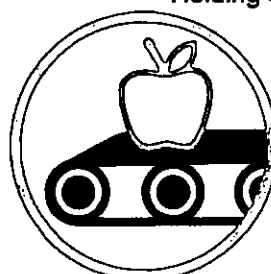
Self-Service Condiment  
Areas, Condiment Containers



Delicatessen Slicer



Conveyor Belts,  
Conveyor Lines,  
Hopper Trays,  
Holding Containers



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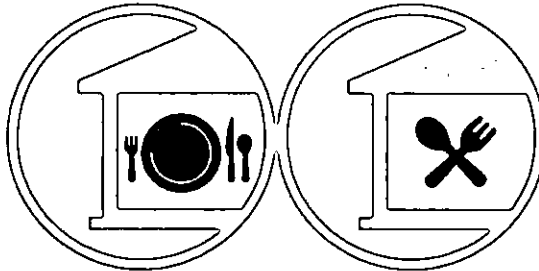
Mar 24, 2016

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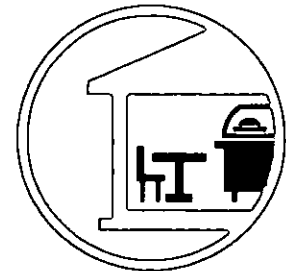
Small Wares  
(beverage dispensers,  
food mixers, scales)



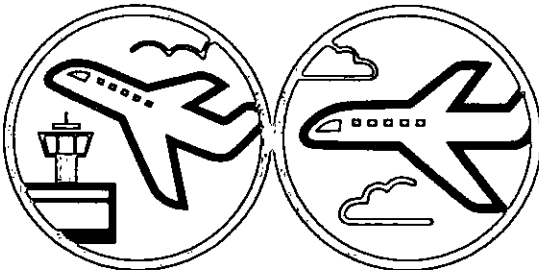
Restaurants  
Foodservice



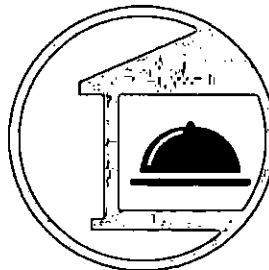
Dining Halls/Cafeterias



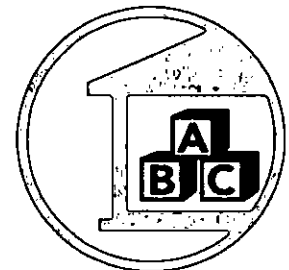
Airplanes/Airports



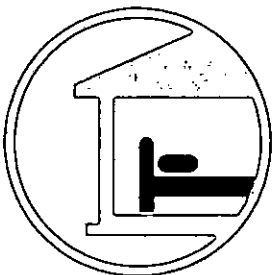
Caterers



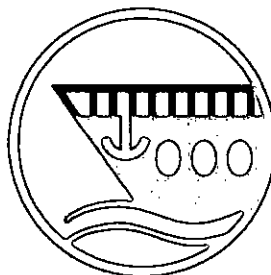
Daycare Settings



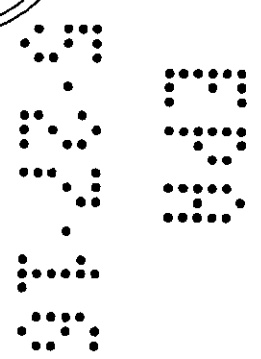
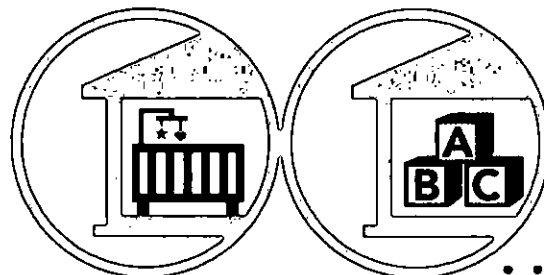
Hotels/Motels



Cruise Ships



Nurseries



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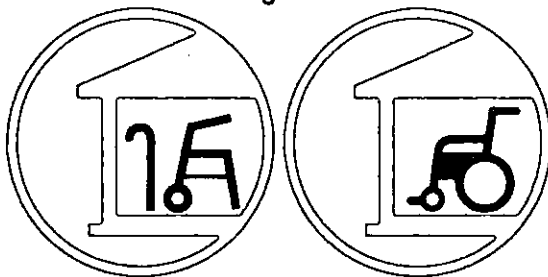
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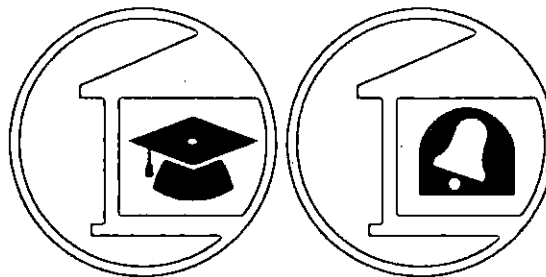
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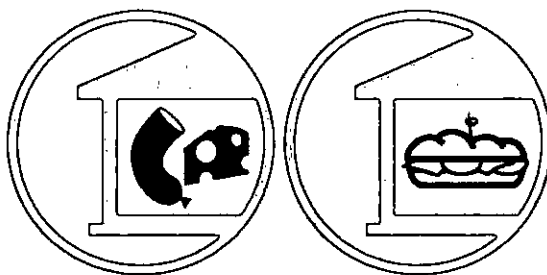
Nursing Homes



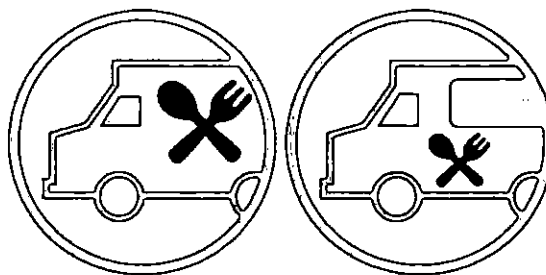
Schools



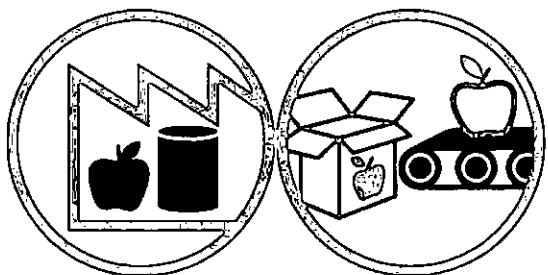
Delicatessens



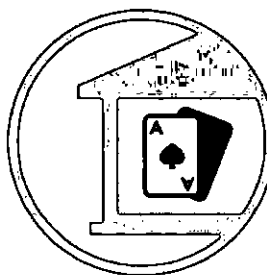
Food Trucks



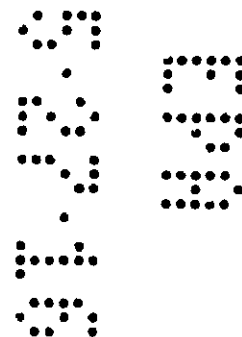
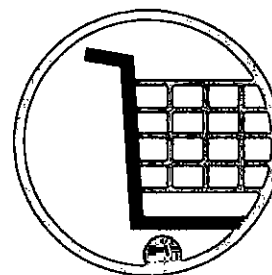
Food Manufacturing Facilities



Casinos



Grocery



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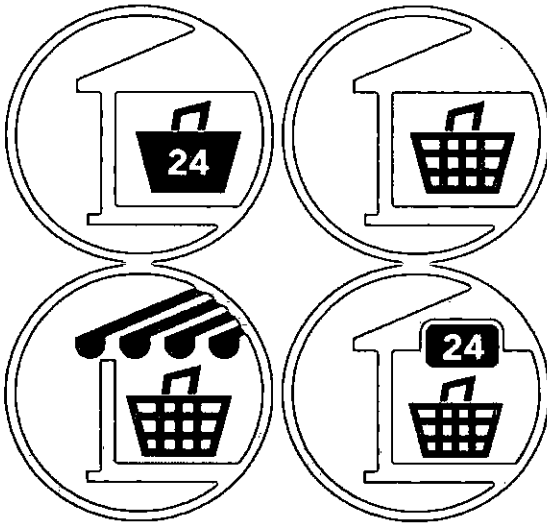
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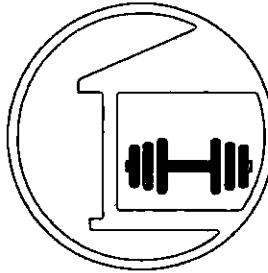
Mar 24, 2016

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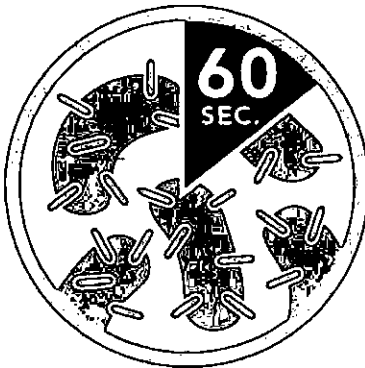
Convenience Stores



Fitness



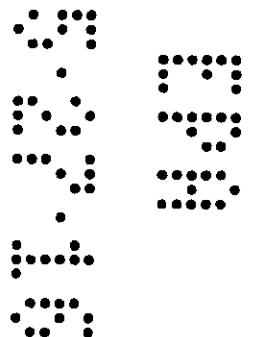
Kills Listeria in 60 seconds



Kills Listeria in 1 minute



[Logo]



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# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 10-21-15

Experts In-Processing Signature: B.B.

Date 10-23-15

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>9480-RC</u>		EPA Receipt Date: <u>10-21-15</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

**Comments:**

\* Documentation: (Pass) / Fail

- required forms are complete

\* Inserts: (Pass) / Fail

- Inserts approved for food use for use in antimicrobial formulations.

\* PRN 11-15: (Pass) / Fail

MRZD: 497464

SLC 11-3-15

\* Overall Status: (Pass) / Fail

\* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### **Conventional New Product Applications**

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

## A540 - New end use product.

- Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.
- Data waivers may be requested. Chemistry data on the TGAi in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAi)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAi Data Submitted
830.1550	Product Identity & Composition	✓		
830.1600	Description of materials used to produce the product	✓		
830.1650	Description of formulation process	✓		
830.1670	Discussion on the formation of impurities	✓		
830.1700	Preliminary analysis	✓		
830.1750	Certified limits (158.345)	✓		
830.1800	Enforcement analytical method	✓		

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAi Data Submitted
830.6302	Color	✓		
830.6303	Physical State	✓		
830.6304	Odor	✓		
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓		
830.6315	Flammability	✓		
830.6316	Explosibility	✓		
830.6317	Storage stability*	✓		
830.6319	Miscibility	✓		
830.6320	Corrosion Characteristics*	✓		
830.6321	Dielectric Breakdown Voltage	✓		
830.7000	pH	✓		
830.7050	UV/ Visible Absorption			
830.7100	Viscosity	✓		
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density	✓		
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required

\*May not be included with initial application



## A540 - Acute Toxicity Requirements

New products must either:

- 1) supply the product specific acute toxicity 6 pack data (listed below);
- 2) provide a bridging rationale document or waiver request or,
- 3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)		✓		
830.1200	Acute Dermal (LD50)		✓		
830.1300	Acute Inhalation (LC50)		✓		
830.2400	Acute Eye Irritation		✓		
830.2500	Acute Dermal Irritation		✓		
830.2600	Dermal Sensitization		✓		

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number  
**Professional Disposables International, Inc. (PDI)**  
**c/o Delta Analytical Corp.**  
**12510 Prosperity Drive, Suite 160, Silver Spring, MD 20904**

EPA Registration Number/File Symbol  
**9480-**

Active Ingredient(s) and/or representative test compound(s)  
**Didecyl dimethyl ammonium chloride AND**  
**Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride**

Date  
**10/09/15**

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)  
**Domestic indoor**

Product Name  
**Backspin No-Rinse FCSS**

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA For 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (The Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product or identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite the study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (1) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

*Cristina Griffin*

Date  
**10/09/15**

Typed or Printed Name and Title  
**Cristina Griffin, Agent for PDI**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

DATA MATRIX – END USE

Date 10/09/15	EPA Reg. No./File Symbol 9480-	Page 1 of 1
Applicant's/Registrant's Name & Address Professional Disposables International, Inc. (PDI) c/o Delta Analytical Corp., 12510 Prosperity Drive, Suite 160, Silver Spring, MD 20904		Product Backspin No-Rinse FCSS

Ingredients: Didecyl dimethyl ammonium chloride, Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride

Guideline Reference #	Guideline Study Name	MRID Number	Submitter	Status	Note
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PRODUCT CHEMISTRY - PROD. IDENTITY, COMP. & ANALYSIS


830.1550-830.1800	Product Identity, Manufacturing Process, and Analytical Method	To be assigned 49686301	PDI	OWN	
830.1900	Submittal of Samples	N/A	N/A	N/A	Available U-Request
830.6302-830.7300	Physical and Chemical Properties	To be assigned 49686302	PDI	OWN	

TOXICITY

870.1100	Acute Oral Toxicity Study in Rats	49686303	PDI	OWN	
870.1200	Acute Dermal Toxicity Study in Rabbits	49686304	PDI	OWN	
870.1300	Acute Inhalation Toxicity Study in Rats	49686305	PDI	OWN	
870.2400	Acute Eye Irritation Study in Rabbits	49686306	PDI	OWN	
870.2500	Acute Dermal Irritation Study in Rabbits	49686307	PDI	OWN	
870.2600	Skin Sensitization Study in Guinea Pigs	49686308	PDI	OWN	

PRODUCT PERFORMANCE

810.2300	PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: Staphylococcus aureus (ATCC 6538) Glass and Rough Plastic- 4ft. <sup>2</sup>	To be assigned	PDI	OWN	
	PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: Escherichia coli (ATCC 11229) Glass and Rough Plastic- 4ft. <sup>2</sup>	To be assigned	PDI	OWN	
	PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: Shigella boydii (ATCC 9207) Glass and Rough Plastic- 4ft. <sup>2</sup>	To be assigned	PDI	OWN	
	PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: Listeria monocytogenes (ATCC 19115) Glass and Rough Plastic- 4ft. <sup>2</sup>	To be assigned	PDI	OWN	
	Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modified for Pre-Saturated Towelette Product Application): Enterobacter aerogenes (ATCC 13048), Staphylococcus aureus (ATCC 6538)	To be assigned	PDI	OWN	
	Germicidal and Detergent Sanitizing Action of Disinfectants: Staphylococcus aureus (ATCC 6538)	49686309	PDI	OWN	
	Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces: Enterobacter aerogenes (ATCC 13048), Staphylococcus aureus (ATCC 6538)	49686310	PDI	OWN	
	Germicidal and Detergent Sanitizing Action of Disinfectants: Escherichia coli (ATCC 11229)	49686313	PDI	OWN	
	Germicidal and Detergent Sanitizing Action of Disinfectants: Listeria monocytogenes (ATCC 19117)	49686315	PDI	OWN	
	Germicidal and Detergent Sanitizing Action of Disinfectants: Shigella boydii (ATCC 9207)	49686318	PDI	OWN	

Signature 	Name and Title Cristina Griffin, Agent for PDI	Date 10/0915
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

DATA MATRIX – END USE

Date 10/09/15

EPA Reg. No./File Symbol 9480-

Page 1 of 1

Applicant's/Registrant's Name & Address Professional Disposables International, Inc. (PDI)  
c/o Delta Analytical Corp., 12510 Prosperity Drive, Suite 160, Silver Spring, MD 20904

Product Backspin No-Rinse FCSS

Ingredients: Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride AND Didecyl dimethyl ammonium chloride

Guideline Reference #	Guideline Study Name	MRID Number	Submitter	Status	Note
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PRODUCT CHEMISTRY - PROD. IDENTITY, COMP. & ANALYSIS

	PDI	OWN	
	N/A	N/A	Available Upon Request
	PDI	OWN	

TOXICITY

	PDI	OWN	
	PDI	OWN	
	PDI	OWN	
	PDI	OWN	
	PDI	OWN	
	PDI	OWN	

PRODUCT PERFORMANCE

	PDI	OWN	
	PDI	OWN	
	PDI	OWN	
	PDI	OWN	
	PDI	OWN	
	PDI	OWN	
	PDI	OWN	
	PDI	OWN	
	PDI	OWN	
	PDI	OWN	

Signature 	Name and Title Cristina Griffin, Agent for PDI	Date 10/09/15
-----------------------------------------------------------------------------------------------	---------------------------------------------------	------------------

**EPA**

United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

## Applicant's Name and Address

Professional Disposables International, Inc. (PDI)  
Two Nice-Pak Park  
Orangeburg, NY 10962

## EPA File Symbol/Registration Number

9480-

## Product Name

Backspin No-Rinse FCSS

## Date of Confidential Statement of Formula (EPA Form 8570-4)

10/09/15

As an authorized representative of the applicant for registration of the product identified above, I certify that:

## (1) This product contains the following active ingredient(s):

Didecyl Dimethyl Ammonium Chloride

AND

Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

## (3) Indicate by checking (A) or (B) below which paragraph applies:

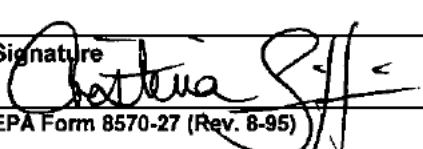
☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

## (4) The following active ingredients in this product qualify for the formulator's exemption.

## Source

Active Ingredient	Product Name	Registration Number
Didecyl Dimethyl Ammonium Chloride		
Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride	*Product ingredient source information may be entitled to confidential treatment*	
Signature 	Name and Title Cristina Griffin	Date 10/09/15

EPA Form 8570-27 (Rev. 8-95)

\*U.S. GSA: 1995-386-820/20413

White - EPA copy  
Yellow - Applicant copy

g:\epa\formula

## Transmittal Document

### Submitter:

Professional Disposables International, Inc. (PDI)  
Two Nice-Pak Park  
Orangeburg, NY 10962-1376

### Company Contact:

Cristina Griffin, Delta Analytical Corporation  
Agent for PDI  
12510 Prosperity Drive, Suite 160  
Silver Spring, MD 20904

### Regulatory Action in Support of Which this Package is Submitted:

Application for Registration of Backspin No-Rinse FCSS

### Submission Date:

October 20, 2015

### Submitted Studies:

Volume 1: Product Identity, Manufacturing Process, and Enforcement Analytical Method

Volume 2: Physical and Chemical Properties

Volume 3: PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Staphylococcus aureus* (ATCC 6538) Glass and Rough Plastic- 4ft.<sup>2</sup>

Volume 4: PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Escherichia coli* (ATCC 11229) Glass and Rough Plastic- 4ft.<sup>2</sup>

Volume 5: PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Shigella boydii* (ATCC 9207) Glass and Rough Plastic- 4ft.<sup>2</sup>

Volume 6: PDI Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces: *Listeria monocytogenes* (ATCC 19115) Glass and Rough Plastic- 4ft.<sup>2</sup>

Volume 7: Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modified for Pre-Saturated Towelette Product Application): *Enterobacter aerogenes* (ATCC 13048), *Staphylococcus aureus* (ATCC 6538)



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number **9480-**2. EPA Product Manager  
**Eric Miederhoff**

3. Proposed Classification

☐ None ☐ Restricted4. Company/Product (Name) **Backspin No-Rinse FCSS**PM# **31**

5. Name and Address of Applicant (Include ZIP Code)

**Professional Disposables International, Inc. (PDI)****c/o Delta Analytical Corp.****12510 Prosperity Drive, Suite 160****Silver Spring, MD 20904**

Check if this is a new address

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No.: \_\_\_\_\_

Product Name: \_\_\_\_\_

## Section - II

☐ Amendment - Explain below  
☐ Resubmission in response to Agency letter dated \_\_\_\_\_  
☐ Notification - Explain below.

☐ Final printed labels in response to Agency letter dated \_\_\_\_\_  
☐ "Me Too" Application.  
☒ Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

**Application for Registration of Backspin No-Rinse FCSS; PRIA Fee Category: A540 (receipt attached); Decision time: 5 months; Fee: \$5107; Contact name: Cristina Griffin, Agent for PDI. email: cgriffin@delta-ac.com**

## Section - III

1. Material this Product will be Packaged in:

Child-Resistant Packaging  
☐ Yes\* For retail  
☒ No

Unit Packaging  
☒ Yes  
☐ No

Water Soluble Packaging  
☐ Yes  
☒ No

2. Type of Container

☐ Metal  
☒ Plastic  
☐ Glass  
☐ Paper  
☒ Other (Specify):

Plastic Pack

\* Certification must  
be submitted

If "Yes,"  
Unit Package wgt. No. per  
Container  
0.13 lbs. 1 per packet  
(4 per package)

If "Yes,"  
Unit Package wgt. No. per container

3. Location of Net Contents Information

☒ Label ☐ Container4. Size(s) of Retail Container  
1-4 lbs. (100-180 wipes)

5. Location of Label Direction

☒ On Label or:  
☐ On Labeling accompanying product

6. Manner In Which Label Is Affixed to Product

☐ Lithograph ☒ Paper glued ☐ Stenciled☒ Other: Gravure or flexographic printing; directly onto container

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name  
**Cristina Griffin**Title  
**Agent for PDI**Telephone No. (Include Area Code)  
**301-680-7971**

## Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any kind of knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature

3. Title  
**Agent for PDI**4. Typed Name  
**Cristina Griffin**5. Date  
**October 20, 2015**

Date Application  
Received  
(Stamped)



October 20, 2015

Document Processing Desk (APPL)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
2777 S. Crystal Drive, Room S-4900  
Arlington VA 22202

Attn: Eric Miederhoff, PM 31

**Re: Application for New Registration: Backspin No-Rinse FCSS**  
**PRIA Fee Category: A540 (receipt attached to application form); Decision time: 5 months; Fee: \$5,107**  
Product is based on the EPA file symbol 9480-RR, Backspray RTU  
**Company: Professional Disposables International, Inc.**  
**Product Name: Backspin No-Rinse FCSS**  
**File Symbol: 9480-**

Dear Mr. Miederhoff:

On behalf of Professional Disposables International, Inc. (PDI), I am submitting an application for a new end-use registration for the product Backspin No-Rinse FCSS (EPA file symbol 9480-). Certain data requirements are being bridged from Backspray RTU, currently under EPA review to be registered (EPA file symbol 9480-RR).

**PRIA:**

This product is in PRIA Fee Category A540, \$5,107 fee paid in advance (receipt attached to application form), 5 month time frame. This product contains active ingredients and uses included in other EPA registered end use products.

**CSF:**

Backspin No-Rinse FCSS is a sanitizing wipe for hard nonporous food and nonfood contact surfaces. With the exception of the towelette material, the formulation is identical to the Backspray RTU (9480-RR), which is currently being reviewed at EPA.

**Label:**

The Backspin No-Rinse FCSS label is substantially similar to the Backspray RTU (9480-RR) product label. The towelette claims are similar to claims on other EPA approved PDI wipe product labels.

**Chemistry Data**

To support Backspin No-Rinse FCSS, we are citing chemistry data from the Backspray RTU (9480-RR), as well as submitting Part A and Part B chemistry data on the wipe. In conformance with the 810 guidelines, the Part A chemistry data include the wipe characterization assay.



Toxicity Data

To support Backspin No-Rinse FCSS, we are citing toxicity data from the Backspray RTU (9480-RR), currently being reviewed.

Efficacy Data:

To support Backspin No-Rinse FCSS organism claims on the label, we are citing efficacy studies conducted on the Backspray RTU (9480-RR) for those specific claims. In addition, in accordance with EPA's OCSP 810.2300 guidelines (2012) and EPA's "Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes" (April 12, 2001), PDI is submitting four studies for efficacy testing conducted on the towelette. Also enclosed is one study for testing conducted on the towelette as a non-food contact sanitizer.

Enclosures

The following documents are enclosed in support of this application:

- Transmittal Document
- EPA form 8570-1
- Receipt to show payment of PRIA fee (attached to application)
- Certification with Respect to Citation of Data
- End Use Data Matrix – Internal and External Copies
- Formulator's Exemption Statement
- Confidential Statement of Formula: Basic (2 copies)
- Five copies of label
- Three sets of 7 study volumes listed in attached transmittal

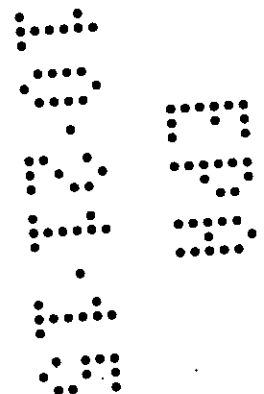
If you have any questions please contact me at [cgriffin@delta-ac.com](mailto:cgriffin@delta-ac.com) or (301) 680-7971.

Sincerely,



Cristina Griffin  
Agent for PDI

cc: Jean Claude Marcelin, PDI



**Receipt for Section 3**

S: 975899

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Company: 9480 PROFESSIONAL DISPOSABLES INTERNATIONAL

Billable: ☒ Yes ☐ No

Print Letter

Enter More Information

Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 31

Product #:  Product Name: BACKSPIN NO-RINSE FCSS

Override#:

Me Too Section3:  Me Too Product Name:

Application Date:

OPP Rec'd Date:

Front End Date:

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Receipt Content

Study

CSF

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

# PRIA Fee Receipt

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or [yanchulis.michael@epa.gov](mailto:yanchulis.michael@epa.gov).

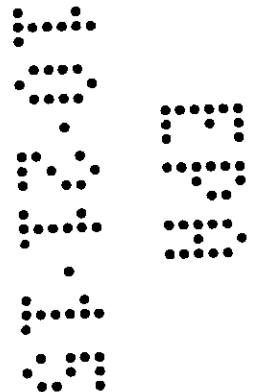
Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 25NRNQ2C  
Agency Tracking ID: 74889491446

Account Holder Name: Professional Disposables International Inc.  
Transaction Type: ACH Debit  
Transaction Amount: \$5,107.00  
Payment Date: 10/14/2015  
Account Type: Business Checking  
Routing Number: 053101561  
Account Number: \*\*\*\*\*2541

Transaction Date: 10/13/2015 09:17:14 AM EDT  
Total Payments Scheduled: 1  
Frequency: OneTime

Registration Number:  
Company Name: Professional Disposables  
Company Number: 9480  
Action Code: A540

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



Pages 120-128 - \*Confidential Statements of Formula may be entitled to confidential treatment\*